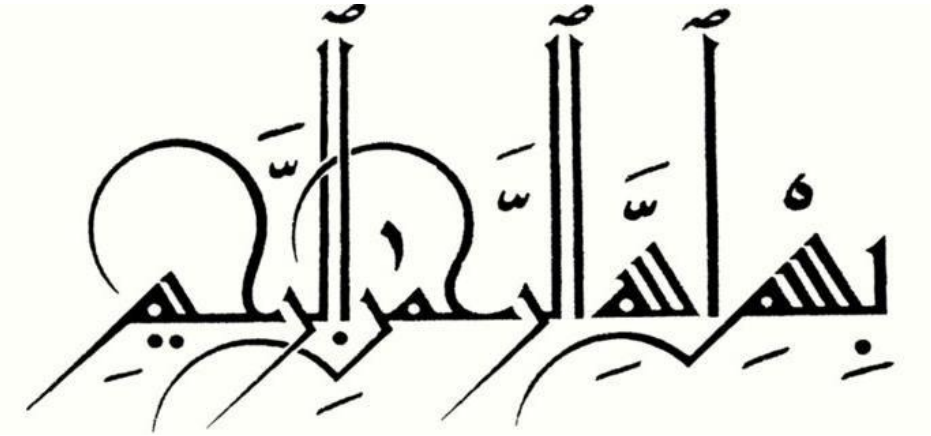
Rawalpindi Medical University Rawalpindi

Clinical Trial Unit Report 2024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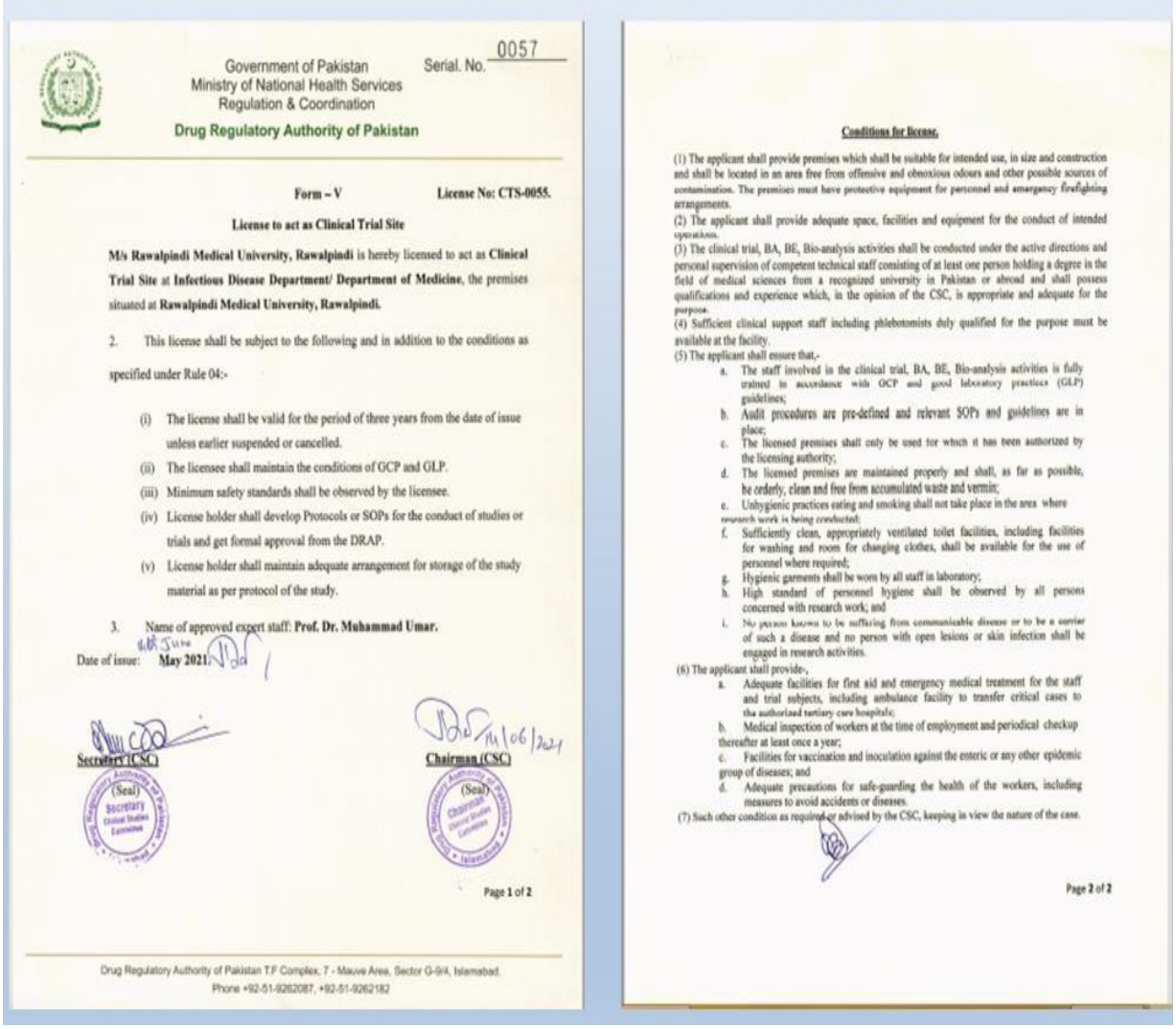

Government of Pakistan
Ministry of National Health Services
Regulation & Coordination
Drug Regulatory Authority of Pakistan

Serial. No. 0057

Form – V License No: CTS-0055.

License to act as Clinical Trial Site

M/s Rawalpindi Medical University, Rawalpindi is hereby licensed to act as **Clinical Trial Site** at **Infectious Disease Department/ Department of Medicine**, the premises situated at **Rawalpindi Medical University, Rawalpindi.**

2. This license shall be subject to the following and in addition to the conditions as specified under Rule 04:-

(i) The license shall be valid for the period of three years from the date of issue unless earlier suspended or cancelled.
(ii) The licensee shall maintain the conditions of GCP and GLP.
(iii) Minimum safety standards shall be observed by the licensee.
(iv) License holder shall develop Protocols or SOPs for the conduct of studies or trials and get formal approval from the DRAP.
(v) License holder shall maintain adequate arrangement for storage of the study material as per protocol of the study.

3. Name of approved expert staff: **Prof. Dr. Muhammad Umar.**

Date of issue: **May 2021.**

Secretary (CSC) (Seal) Secretary

Chairman (CSC) 11/06/2021 (Seal) Chairman

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Drug Regulatory Authority of Pakistan T.F Complex, 7 - Mauve Area, Sector G-9/4, Islamabad.
Phone +92-51-9262087, +92-51-9262182

Conditions for license.

(1) The applicant shall provide premises which shall be suitable for intended use, in size and construction and shall be located in an area free from offensive and obnoxious odours and other possible sources of contamination. The premises must have protective equipment for personnel and emergency firefighting arrangements.
(2) The applicant shall provide adequate space, facilities and equipment for the conduct of intended operations.
(3) The clinical trial, BA, BE, Bio-analysis activities shall be conducted under the active directions and personal supervision of competent technical staff consisting of at least one person holding a degree in the field of medical sciences from a recognized university in Pakistan or abroad and shall possess qualifications and experience which, in the opinion of the CSC, is appropriate and adequate for the purpose.
(4) Sufficient clinical support staff including phlebotomists duly qualified for the purpose must be available at the facility.
(5) The applicant shall ensure that,-
a. The staff involved in the clinical trial, BA, BE, Bio-analysis activities is fully trained in accordance with GCP and good laboratory practices (GLP) guidelines;
b. Audit procedures are pre-defined and relevant SOPs and guidelines are in place;
c. The licensed premises shall only be used for which it has been authorized by the licensing authority;
d. The licensed premises are maintained properly and shall, as far as possible, be orderly, clean and free from accumulated waste and vermin;
e. Unhygienic practices eating and smoking shall not take place in the area where research work is being conducted;
f. Sufficiently clean, appropriately ventilated toilet facilities, including facilities for washing and room for changing clothes, shall be available for the use of personnel where required;
g. Hygienic garments shall be worn by all staff in laboratory;
h. High standard of personnel hygiene shall be observed by all persons concerned with research work; and
i. No person known to be suffering from communicable disease or to be a carrier of such a disease and no person with open lesions or skin infection shall be engaged in research activities.
(6) The applicant shall provide-,
a. Adequate facilities for first aid and emergency medical treatment for the staff and trial subjects, including ambulance facility to transfer critical cases to the authorized tertiary care hospitals;
b. Medical inspection of workers at the time of employment and periodical checkup thereafter at least once a year;
c. Facilities for vaccination and inoculation against the enteric or any other epidemic group of diseases; and
d. Adequate precautions for safe-guarding the health of the workers, including measures to avoid accidents or diseases.
(7) Such other condition as required or advised by the CSC, keeping in view the nature of the case.

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License to Act as Clinical Trial Site- Rawalpindi medical university by DRAP

Team

Rawalpindi Medical University -Clinical Trial Unit

Patron-in-chief

Dr. Muhammad Umar, **Sitra -i- Imtiaz, Hilal-i- Imtiaz Vice Chancellor**

Dr. Muhammad Mujeeb Khan, Associate Professor Infectious Disease

Dr. Attiya Munir	Chairperson department of Pharmacology & Therapeutics
Dr. Shanila Akhter	Director CTU, Assistant Prof. IPFP
Dr. Akram Randhawa	Associate Director Research
Dr. Saima Ambreen	Associate Professor Medicine Unit I
Dr Tayyab Saeed Akhter	Senior Registrar Gastroenterology, HFH)
Dr Sarah Rafi	Research Coordinator

Contributors

Dr Shanila Akhter	Director CTU (Written and compiled)
Dr Attiya Munir	Head of Department of Pharmacology (Editor)
Amir Shahzad	Librarian NTB RMU

Mission

To provide scientific mentorship for coordinators and investigators, as well as regulatory guidance statistical resources and manuscript support to assist investigators in the development and implementation of research ideas

Vision

Provisioning of authentic research grounds for the development of new drugs for the betterment of clinical care, while ensuring human safety before, during, and after a research study.

Core Values

Message from Vice Chancellor

Clinical research plays a vital role in modern healthcare. Clinical trials help determine the safety and effectiveness of pharmaceutical drugs and medical devices before being marketed for mass consumption. Distinguishing strengths hospitals bring to clinical research and an understanding of the critical role clinical research can play in preparing hospitals and healthcare systems for the future needs no emphasis.

Through clinical research, hospitals can be better positioned to improve quality of care, test and adopt cutting-edge products/ practices and meet the unique healthcare needs of the patients and communities they serve. Unfortunately, clinical research and clinical trials, have not been central to the mandate of community hospitals in Pakistan. Inadequacy of our entire healthcare chain was greatly visible due to total dependency on foreign made vaccines during Covid-19 pandemic.

Therefore, it has become critical than ever before for our hospitals to lead clinical research programs that can better serve the specific health needs of country's' patient population; fill gaps in clinical research; provide more equitable access to clinical research for under-represented patient groups and address imperatives central to all hospitals and healthcare systems.

Establishment of Clinical Trials Unit by RMU is an effort to support indigenous efforts in drugs development in Pakistan. Unit has been made fully functional within short span of three years by my highly dedicated team of professionals and I am confident that Clinical Trials Unit will greatly contribute towards improving the quality, cost-effectiveness and clinical outcomes of healthcare in the country.

PROF. MUHAMMAD UMAR, *Sitara-i-Imtiaz, Hilal-i-Imtiaz*
MBBS, MCPS, FCPS, FRCP(G), FRCP(L), FACG, AGAF, FASGE
Vice Chancellor / Chief Executive / Professor of Medicine Rawalpindi Medical University & Allied Hospitals Gastroenterologist and Hepatologist, Holy Family Hospital
Clinical Coordinator Hepatitis Prevention and Control Program Chairman WGO Hepatitis C Treatment Guidelines Committee First Governor of American College of Gastroenterology (ACG) Past President Pakistan Society of Gastroenterology (PSG)
Past President Pakistan Society of Hepatology (PSH) Past President Rawalians
President Rawalian Research Forum past Chairman Asiahep Pakistan

Message from Chairperson CTU

Dr Attiya Munir, MBBS, MPhil Pharmacology

Importance of continuous research for clinical care and health education needs no more emphasis. Education, clinical care and research are the cornerstones for teaching health centres. Rawalpindi medical university has the mission to impart evidence-based research oriented medical education and to provide best possible patient care.

Clinical Trial Units (CTUs) have been set up with a purpose to design, conduct, analyze and publish clinical trials and other well- designed studies which can be monitored at any stage by the regulatory bodies. Establishment of Clinical Trials Unit was a huge challenge for a public sector University in Pakistan due to lack of authentic research culture. It was the leadership, guidance and support of Worthy Vice Chancellor Professor Muhammad Umar, which enabled smooth formation of a fully functional CTU at RMU to conduct safe and efficient clinical trials for new treatment interventions.

Each member of CTU team is proud of actively participating in actualization of the vision to provide better health care to our patients through indigenous research in medicine domain. We are highly appreciative of all our industrial partners, regulatory bodies, principal investigators and sponsors for their trust on RMU. Together we will fully endeavour to break new grounds for patient care in Pakistan for which integrity, innovation and patient safety will remain to be our core values.

Message from the Director

Dr Shanila Akhter, PhD Pharmacology, MPhil Pharmacology,
Pharm D, University of Sargodha

At the heart of our mission lies a steadfast commitment to advancing medical research and improving patient outcomes through innovative and rigorous clinical trials. We believe that every study we undertake has the potential to bring us one step closer to breakthroughs that can change lives. our researchers and staff, your tireless efforts, expertise, and passion drive the success of our trials. Your work ensures that we produce reliable and impactful results that can lead to significant advancements in healthcare. I am continually inspired by your dedication and commitment to excellence.

To our partners and collaborators, thank you for your continued support and collaboration. Together, we are building a future where innovative treatments can reach those who need them most, faster and more efficiently.

In the coming year, we are excited to launch several new trials that have the potential to make groundbreaking contributions to medical knowledge and patient care. We are also enhancing our processes and infrastructure to ensure that our trials run smoothly and that our participants have the best possible experience.

Thank you all for your unwavering support and dedication. We are proud to work alongside you in our shared mission to advance medical research and improve health outcomes for all.

Acknowledgements

First and foremost, we are grateful to the Almighty Allah for granting us the strength and blessings to successfully establish Clinical Trial Unit (CTU) at RMU. We are highly thankful for the valuable guidance, direction and encouragement provided by worthy Vice Chancellor Professor Dr. Muhammad Umar, Rawalpindi medical University that resulted in award of Clinical Test Site license to RMU. We are grateful to the tireless efforts of Associate Professor Dr. Muhammad Mujeeb Khan (Chairperson Department of Infectious Diseases, RMU) for the completion of the registration formalities. We highly appreciate the contributions of all HODs and staff members of departments of Rawalpindi Medical University and Allied Hospitals throughout the entire process of establishment of CTU and subsequent conduct of clinical trials.

Disclaimer

The information provided in this repository is for general information only. The information and details regarding the clinical trials activities have been prepared in co-ordination with Researchers of respective departments of Rawalpindi Medical University, Principal investigators and our Sponsors.

We endeavored to keep the information complete and accurate. However, we make no representations or warranties of any kind, express or implied, regarding the completeness, accuracy and reliability of this information. We cannot accept any legal responsibility or liability of any errors or omissions that may be made. Also, we cannot accept liability for damage or loss of profit, arising from any errors or omissions.

Standard Operating Procedures (SOPs)

Standard Operating Procedures (SOPs) for a Clinical Trial Unit (CTU) are essential documents that ensure compliance with regulatory requirements, maintain the integrity of data, and protect the rights and safety of study participants. Here is a structured outline and some example SOPs that a CTU might follow:

Infrastructure Development

Establish a Dedicated Facility: Develop state-of-the-art facilities equipped with research labs, data management systems, and patient care areas and also adopt **Digital Transformation** that is helpful for the management and to maintain the record of clinical trials.

RMU-CTU Office

This is comprised of CTU OPD room in Holy family hospital entitled with name plate clinical trials unit/ research area.

CTU –OPD ROOM

This room is typically used for conducting clinical trial-related consultations, screenings, and follow-ups with study participants. It is an essential part of the CTU infrastructure, ensuring patient privacy and compliance with trial protocols.

Trained Staff:

Organize training programs for investigators, study coordinators, and clinical staff on Good Clinical Practice (GCP) guidelines and trial protocols.

RMU-CTU Recovery Room:

Equipped with monitors for tracking vital signs like heart rate, blood pressure, oxygen saturation, and respiration and also includes adjustable beds, privacy curtains, and controlled temperature for participant comfort.

It also contains essential items such as oxygen tanks, defibrillators, and emergency medications and staffed by trained medical professionals, such as nurses or clinical research associates, to provide immediate care if needed.

Collaborate with Experts:

Engage with statisticians, epidemiologists, and clinical research professionals to build a multidisciplinary team. Furthermore, encourage medical students and postgraduate trainees to participate in research projects and understand the importance of evidence-based medicine. And Host regular workshops and guest lectures on the latest trends and regulatory requirements in clinical trials.

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Clinical Trial Unit Standard Operating Process (SOPs)

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Study Management

- Study initiation
- Study conduct
- Study closeout

Regulatory Compliance

- Good Clinical Practice (GCP) guidelines
- Ethical considerations
- Institutional Review Board (IRB) interactions

Participant Recruitment and Enrollment

- Recruitment strategies
- Informed consent process
- Eligibility criteria

Data Management

- Data collection and entry
- Data storage and security
- Data analysis and reporting

Safety Monitoring and Reporting

- Adverse event reporting
- Serious adverse event (SAE) management
- Safety monitoring committees

SOP for Study Initiation

- Procedure for study start-up meetings
- Preparation and distribution of study documentation
- Investigator site file setup

SOP for Informed Consent Process

- Steps for obtaining informed consent
- Documentation and record keeping
- Handling participant questions and concerns

SOP for Data Collection and Management

- CRF (Case Report Form) completion guidelines
- Data entry and verification
- Data correction and query resolution

SOP for Adverse Event Reporting

- Identification and documentation of adverse events
- Reporting timelines and procedures
- Follow-up and documentation of adverse events

SOP for Informed Consent Process

Title:

SOP for Informed Consent Process

Purpose:

To ensure that the informed consent process is conducted in accordance with regulatory requirements and ethical guidelines.

Scope:

This SOP applies to all clinical trials conducted within the Clinical Trial Unit.

Procedure:

Preparation:

- Ensure the informed consent form (ICF) is approved by the IRB.
- Verify that the ICF includes all required elements as per regulatory guidelines.

Obtaining Consent:

- Approach potential participants in a private and comfortable setting.
- Provide the participant with a copy of the ICF and allow sufficient time to read and understand it.
- Explain the study, including its purpose, procedures, risks, benefits, and alternatives.
- Encourage the participant to ask questions and provide clear, comprehensible answers.

Documentation:

- Obtain the participant's signature on the ICF.
- Ensure the person obtaining consent also signs and dates the ICF.
- Provide a copy of the signed ICF to the participant.
- Retain the original signed ICF in the study file.

Ongoing Consent:

- Reaffirm consent at subsequent visits, especially if there are any changes to the study protocol or new information.

Training:

- Ensure all staff involved in the consent process are trained and competent in obtaining informed consent.
- Maintain records of training.

Responsibilities:

- **Principal Investigator (PI):** Ensures overall compliance with the informed consent process.
- **Study Coordinators**: Conduct the informed consent process and maintain documentation.
- **Clinical Trial Staff:** Support the informed consent process as needed.

References:

- **Good Clinical Practice (GCP) Guidelines**
- **Institutional Review Board (IRB) Policies**
- **Regulatory Agency Guidelines (e.g., FDA, EMA)**

Conclusion

Developing comprehensive SOPs tailored to the specific needs and regulatory environment of the "Clinical Trial Unit" is critical for ensuring the success and integrity of clinical trials. Each SOP should be regularly reviewed and updated to reflect changes in regulations, guidelines, and best practices.

Section I:

Historic Perspective Of (CTU)

Repository Of Clinical Trials 2021-23

Introduction

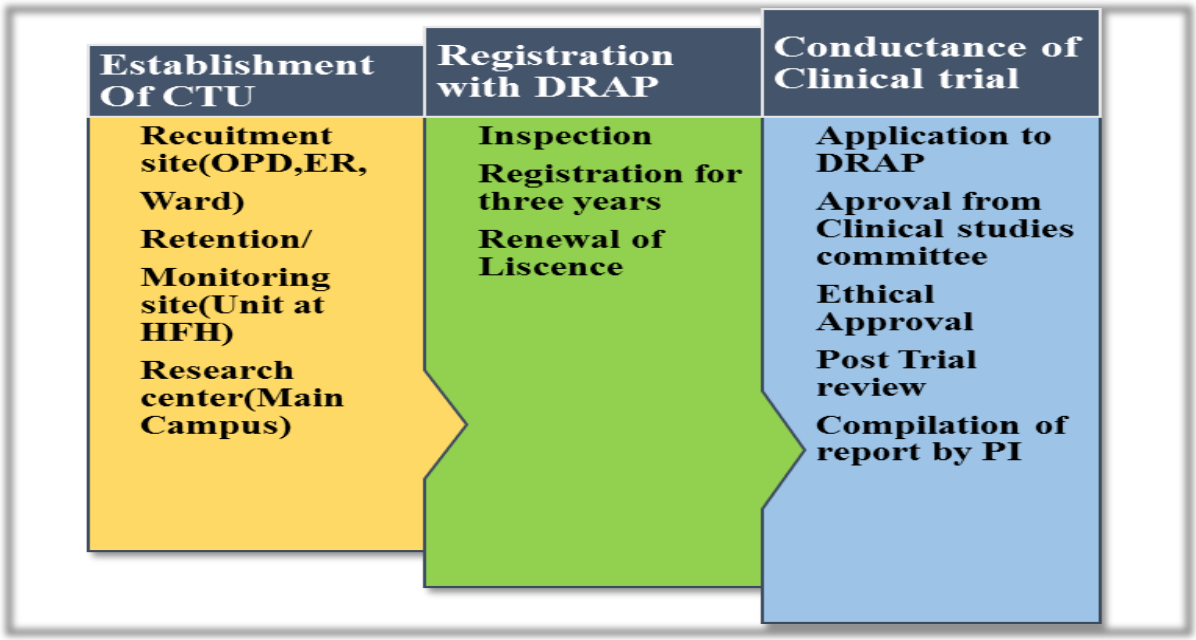
Rawalpindi medical university has the mission to impart evidence-based research oriented medical education and to provide best possible patient care. Under the guidance of worthy Vice Chancellor Professor Dr. Muhammad Umar, Rawalpindi medical University was licensed to act as Clinical Trials Site at Infectious Disease Department/ Department of Medicine in 16th June 2021 to play its role in genuine research and establish linkage between industry and academia

16th June 2021

Road Map to Conduct Clinical Trials

Complete process of establishing a fully functional CTU is as depicted below :-

Process to acquire license as Clinical Trials Site for RMU was initiated with DRAP in April 2021. Focused efforts of CTU core team in general and dedicated approach of Associate Professor Dr. Muhammad Mujeeb Khan (Chairperson Department of Infectious Diseases, RMU) successfully resulted in swift registration of RMU by DRAP as trials site in June 2021. Rawalpindi Medical University is also registered with MedDRA to report any adverse events.



Objectives

Clinical Trial Unit has been established with following objectives:

- To conduct safe and efficient clinical trials for new treatment interventions
- To compare the existing treatment options for more effective use and betterment of the patients
- To explore alternative treatment strategies when the existing ones are not effective
- To provide newer and expensive treatment options to the patients either free of cost or with minimal charges

Organization

- To achieve the above goals and objectives, under the directives of Vice chancellor, Clinical trial unit Committee was formulated that started working enthusiastically from august 2021 onwards. For conduction of safe and efficient trials, Vice chancellor Professor Dr. Muhammad Umar had also allocated an amountof Rs 24.0 Million to establish CTU retention site, funded from HEC.
- CTU under Chairperson Associate Professor Dr Asma Khan (Head of Pharmacology Department) is continuously working to actualize the vision of a fully functional CTU. The Aim of CTU is to develop the culture of conducting clinical trials in RMU that can meet the standards of clinical trials conducted in any advanced country.

CTU–RMU Collaboration meetings

- Physical meeting on 14-06-2024 with Comsat University (Associate Professor Dr. Arafat). Continuous collaboration with Dr Waqas Ahmed that is principal investigator of their project.
- Team meeting at 12:00pm on 7-08-2024 with Searle company regarding project (wanted to evaluate response of patient, post marketing Surveillance – PHASE 4)
- Zoom meeting of clinical trial unit with Sami pharmaceuticals held on 05-09-2024
- (Thursday) at 09:00 AM morning in the respective offices, Rawalpindi Medical University, new campus Rawalpindi. They want to register their project of Vonolia under CTU of RMU
- Physical meetings with Sami pharmaceuticals (clinical trial of Vonolia)

Discus Project with Principal Investigator

Zoom meeting of clinical trial unit with Sami pharmaceuticals held on 05-09-2024 (Thursday) at 09:30 AM morning in the respective offices, Rawalpindi Medical University, new campus Rawalpindi
Physical meeting

Discussion Regarding Adalimumab for Research and their Risk Factor

Discussion With Dr. Bilal Regarding Improvement of CTU in RMU will be held on 13.11.2024 Wednesday at 10:00 am in Syndicate Hall RMU

Types of Clinical Trials Conducted at RMU

RMU is authorized to conduct clinical trials in following categories: -

Registered with DRAP:

Discrepancy with the FDA approved list.

Registered at Institutional Level:

FDA approved drug for a clinical indication/ dose /patient population/phase 3 or above

Guidelines for Researchers

Process

Study Design and Protocol Development:

- Collaborate with investigators to design studies that answer specific research questions.
- Develop detailed protocols that outline study objectives, methodologies, and procedures.

Regulatory Compliance and Ethics:

- Prepare and submit documents for Institutional Review Board (IRB) approval.
- Ensure compliance with Good Clinical Practice (GCP) guidelines and other regulatory standards.

Participant Recruitment and Enrollment:

- Develop and implement strategies to recruit eligible participants.
- Obtain informed consent and ensure participants understand the study's risks and benefits.

Study Implementation:

- Coordinate participant visits, including screenings, treatments, and follow-ups.
- Administer interventions according to the study protocol.
- Monitor participants for adverse events and ensure their safety throughout the trial.

Data Collection and Management:

- Collect and record data accurately and systematically.
- Maintain data integrity and confidentiality.
- Conduct data analysis and assist in interpreting results.

Quality Control and Monitoring:

- Perform regular audits and quality checks to ensure adherence to protocols.
- Address any deviations or issues promptly.

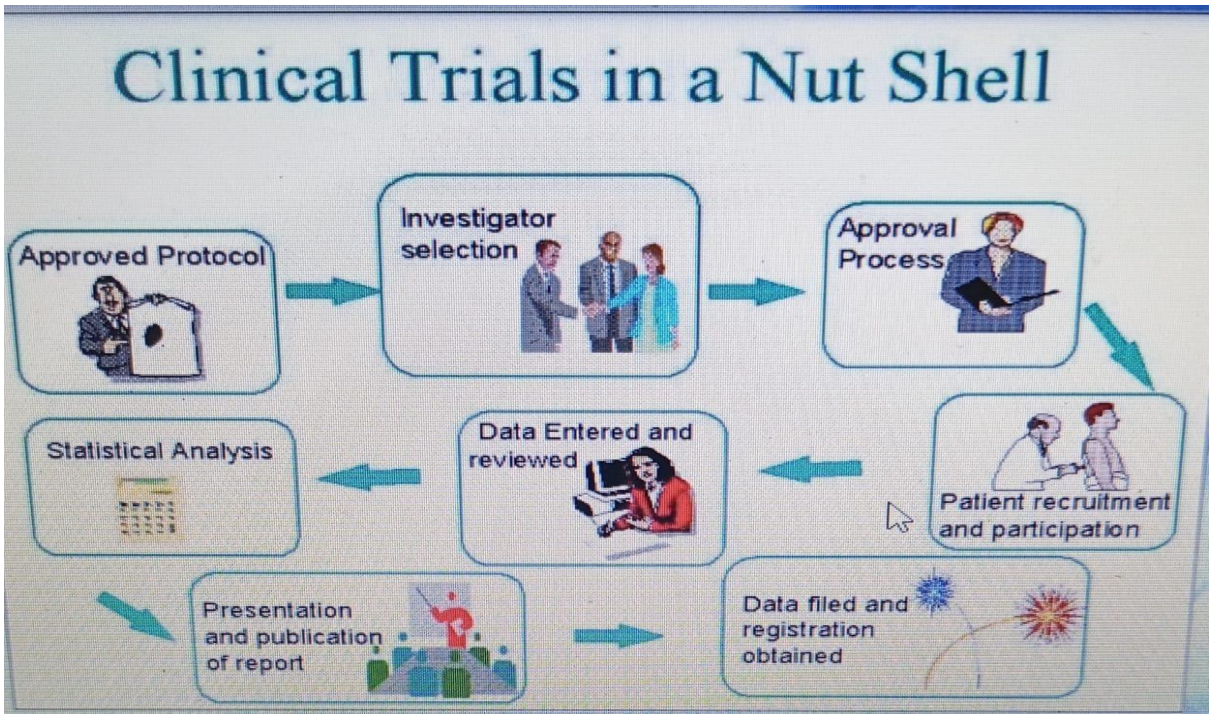
Reporting and Dissemination:

- Prepare reports for sponsors, regulatory authorities, and ethics committees.
- Publish findings in scientific journals and present results at conferences.

Check list for registration of proposal with CTU

- Copy of synopsis
- Letter of IRB
- Consent form
- Trial monitoring report
- Adverse event reporting
- Case report form
- Troubleshoot problems/management /cessation of trial
- Source of funding
- Summary (1 page)

In the period of four months of its establishment, CTU team including Researchers, Principal Investigators and Sponsors was able to initiate three clinical trials, out of which two were registered with DRAP and NIH (USA). Its the dedicated and synergetic efforts of the entire CTU team that today CTU is optimally functional to undertake clinical trials in multiple specialities of medical domain. This document is an effort to present three years overview of these trials in the form of a repository as an appraisal for the RMU top management and as a reference guide to our researchers' investigators as well as industry partners / sponsors.



Section II:

Department Wise Clinical Trials Data: Year 2021

Departmental Clinical Trials Data: Year 2021

Anesthesia			
S No	Topic	CTU Regst No	Status
1	Dexamethasone versus Ondansetron in preventing postoperative nausea and vomiting in laparoscopic surgery	CTU/04/2021/001/ RMU	
2	Effect of dilution of Propofol on pain at site of injection; comparison between 1%vs 0.33% formulation	CTU/04/2021/002/ RMU	
3	Comparison of intraarticular ketorolac versus triamcinolone acetoneinjection in patients of knee osteoarthritis	CTU/04/2021/003/ RMU	
4	Effects of IV Magnesium Sulphate on hemodynamic response to pneumoperitoneum in laparoscopic Cholecystectomy; A randomized control trial	CTU/04/2021/004/ RMU	
5	Caudal Dexmedetomidine Versus Caudal Tramadol as An Adjuvant to Caudal Block With 0.5% Bupivacaine in Pediatric Daycare Surgery - A Randomized Controlled Trial	CTU/04/2021/005/ RMU	
6	Dexamethasone As an Adjuvant for Caudal Blockade In Pediatric Surgical Patients.	CTU/04/2021/006/RMU	
7	Intrathecal Dexmedetomidine Can Decrease The 95% Effective Dose of Bupivacaine in Spinal Anesthesia For Caesarean Section.	CTU/04/2021/007/ RMU	
Otolaryngology (ENT)			
8	Efficacy of platelet rich fibrin in Myringotlasty	CTU/04/2021/008/RMU	
9	Comparison Of Mean Change in Treatment Score of Betahistine andGinkobiloba Extract In Patients With Tinnitis	CTU/04/2021/009/ RMU	
10	Comparison Of Acetic Acid Verses Topical Antibiotics for Otorrhea Resolution in Active CSOM-A Randomized Control Trial.	CTU/04/2021/010/ RMU	

S No	Topic	CTU Regst No	Status
11	A Comparison of Efficacy of Topical Clotrimazole With 3% Salicylic Acid in Otomycosis.	CTU/04/2021/011/ RMU	
12	Endoscopic Dacryocystorhinostomy: With or Without Stenting.	CTU/04/2021/012/ RMU	
Gastroenterology			
13	Patterns of hepatocellular carcinoma after direct antiviral agents and Pegylated Interferon therapy	CTU/04/2021/013/ RMU	
14	Role of probiotic as an add-on therapy in eradicating helicobacter pylori infection.	CTU/04/2021/014/ RMU	
15	Efficacy And Safety Of Tofacitinib As Induction Therapy In Moderate To Severe Ulcerative Colitis	CTU/04/2021/015/ RMU	
16	Immunogenicity And Safety of Hepatitis E Vaccine In Chronic Liver Disease Patient	CTU/04/2021/016/ RMU	
17	Safety And Efficacy of Human Umbilical Cord Derived Mesenchymal Stem Cells for The Treatment Of Moderate And Moderate To Severe Chronic Active Ulcerative Colitis.	CTU/04/2021/017/ RMU	
18	Efficacy And Safety of Vonoprazan in H. Pylori Infection.	CTU/04/2021/018/ RMU	
Medicine			
19	Atherogenic Risk Modification in Type 2 Diabetes- Comparison Between Atorvastatin And Rosuvastatin .	CTU/04/2021/019/ RMU	
20	Efficacy And Safety of Apixaban in Covid- 19 Coagulopathy Patients with Respiratory Severity Under Critical Care.	CTU/04/2021/020/ RMU	

S No	Topic	CTU Regst No	Status
21	Comparison Of Efficacy and Safety of Combination Therapies Empagliflozin/Metformin Versus Sitagliptin/Metformin) In Patients with Uncontrolled Type 2 Diabetes Mellitus on Metformin.	CTU/04/2021/021/ RMU	
22	Efficacy And Safety of Apixaban in Covid-19 Coagulopathy Patients with Respiratory Severity Under Critical Care.	CTU/04/2021/022/ RMU	
Gynecology & Obstetric			
23	Iron supplementation in pregnancy-the most needed but the most neglected element of antenatal care	CTU/04/2021/023/ RMU	
24	Efficacy Of Ascorbic Acid In The Treatment Of Bacterial Vaginosis	CTU/04/2021/024/ RMU	
25	Comparison Of Probiotics with Oral Antibiotics Versus Oral Antibioticsalone in Treatment Of Bacterial Vaginosis.	CTU/04/2021/025/ RMU	
26	Role Of Vitamin D Supplementation with In Reducing the Size of Uterine Leiomyoma in Women With Vitamin D Deficiency.	CTU/04/2021/026/ RMU	
27	Comparison Of Rectally Administered Misoprostol and Oxytocin Infusion for Management of Third Stage of Labor In 2nd Trimester Pregnancy Loss.	CTU/04/2021/027/ RMU	

S No	Topic	CTU Regst No	Status
Ophthalmology (Eye)			
28	Severe recalcitrant fungal keratitis treated with subconjunctival fluconazole as adjunctive therapy	CTU/04/2021/028/ RMU	
29	Effect Of a Single Intraoperative Sub-Tenon Injection Of Triamcinolone Acetonide On Mean Macular Thickness And Visual Outcomes In Diabetic Patients Undergoing Cataract Surgery.	CTU/04/2021/029/ RMU	
Pediatrics			
30	Comparison Of Nebulized Epinephrine and Salbutamol In Treatment Of Bronchiolitis	CTU/04/2021/030/ RMU	
31	Comparison Between Therapeutic Efficacy of Zinc Only and Zinc-Probiotics In Children With Acute Gastroenteritis.	CTU/04/2021/031/ RMU	
32	The Effect of Ursodeoxycholic Acid with PhototherapyinTreatment Of Neonatal Jaundice.	CTU/04/2021/032/ RMU	
33	Effectiveness Of Nebulized Hypertonic Saline for Acute Bronchiolitis in Children.	CTU/04/2021/033/ RMU	
34	Comparison Of Outcomes in Children Suffering From Clinically Symptomatic Hypovitaminosis D Being Given Intramuscular Vitamin D Versus Oral Vitamin D.	CTU/04/2021/034/ RMU	
Pharmacology			
35	Evaluation Of A New Life Style, Two Meals A Day With Only Liquid Meals In Between For The Management Of Gastroesophageal Reflux Disease.	CTU/04/2021/035/ RMU	Pilot study complete d and published

S No	Topic	CTU Regst No	Status
36	Cardio-Pulmonary Protective Role of Hypo-Glycemic Agents Incovid-19 Patients with Diabetes Mellitus And Associated Comorbidities	CTU/04/2021/036/ RMU	
Reconstructive Surgery			
37	Role of topical papaya application in debridement of deep burn wounds	CTU/04/2021/037/ RMU	
Surgery			
38	Comparison of insulin-soaked dressing with the conventional dressing in diabetic ulcers	CTU/04/2021/038/ RMU	
39	Colchicine For the Prevention Of Perioperative Atrial Fibrillation In Patients Undergoing Thoracic Surgery (Cop-Af).	CTU/04/2021/039/ RMU	
Neuro Surgery			
40	Role Of Topical Tranexamic Acid in Spine Surgery: A Randomized Placebo-Controlled Trial	CTU/04/2021/040/ RMU	

Section III:

Department Wise Clinical Trials Data: Year 2022

Departmental Clinical Trials Data: Year 2022

S No	Topic	CTU Regst No	Status
	Anesthesia		
1	Low dose vs highdose oxytocin for initiating uterine contractions during caesarean section	CTU/01/2022/001/RMU	
2	Analgesic effects of US guided quadratus lumborum block during lower abdominal surgeries as compared to I/V analgesia	CTU/01/2022/002/ RMU	
3	Comparison of postoperative recovery time of Propofol and Sevoflurane in patient having laparoscopic cholecystectomy	CTU/01/2022/003/ RMU	
4	Effect of Intrathecal bupivacaine alone and bupivacaine combined with Dexmedetomidine in caesarian section using spinal anesthesia, a comparative study	CTU/01/2022/004/ RMU	
5	Comparison of effects of adding Dexmeditomeidine vs midazolam to intrathecal bupivacaine on postoperative analgesia	CTU/01/2022/005/ RMU	
	Biochemistry		
6	Comparison of efficacy of Duloxetine with Amitriptyline in terms of reduction in frequency of pain in patients of diabetic neuropathy	CTU/01/2022/006/ RMU	
	Dermatology		
7	Efficacy of 5%Tranexamic acid vs 3% Hydroquinone cream in Melasma	CTU/01/2022/007/RMU	
8	Comparison of tropical Tretinoin vs Saliscylic acid peel in the treatment of postinflammatory hyperpigmentation	CTU/01/2022/008/ RMU	
9	Effectiveness of intradermal Transamine in the management of Melasma	CTU/01/2022/009/RMU	

S No	Topic	CTU Regst No	Status
10	Comparison of oral Doxycycline with topical 30% Salicylic acid in treatment of acnevulgaris	CTU/01/2022/010/ RMU	
11	Role of topical Timolol in patientswith infantile hemangioma	CTU/01/2022/011/ RMU	
12	Comparison between efficacy of Minoxidil 5% topicalspray vs PRP in patients with androgenic alopecia	CTU/01/2022/012/ RMU	
13	Role of topical 5% Tranexamic acid in Melasma	CTU/01/2022/013/RMU	
14	Role of Spironolactone in acne	CTU/01/2022/014/RMU	
15	Efficacy of continuous vs pulse dosing of Terbinafine in toenail Onchomycosis	CTU/01/2022/015/RMU	
16	Treatment of Pediatric alopecia areata with Anthralin	CTU/01/2022/016/RMU	
17	Efficacy of IntralesionalVit-D3 in warts	CTU/01/2022/017/RMU	
18	Comparison of oral Fluconazole and Terbinafine for P.versicolor	CTU/01/2022/018/RMU	
19	Efficacy of 85% Lactic acid in treatment of Melanoma	CTU/01/2022/019/RMU	
20	Randomized trial of oral Tranexamic with Fluocinolone based triple cream verses Fluocinolone based triple clean alone for the treatment of Melasma	CTU/01/2022/020/ RMU	
21	Comparison of efficacy of Platelate rich plasma and 5% topical Minoxidil for android genetic alopecia treatment	CTU/01/2022/021/ RMU	
22	Efficacy Of Topical Hydrogen Peroxide 40% For Treatment Of Seborrheic Keratosis.	CTU/01/2022/022/RMU	
23	Comparison Of Topical Tretinoin Versus Salicylic Acid Peel In Treatment Of Post Inflammatory Hyperpigmentation	CTU/01/2022/023/ RMU	

S No	Topic	CTU Regst No	Status
Otolaryngology (ENT)			
24	Clinical outcome of Montelukast sodium in children with adenoids hypertrophy	CTU/01/2022/024/RMU	
25	Comparison of tropical 3% salicylic acid in rectified spirit and Clotrimazole lotion 1% in Otomycosis	CTU/01/2022/025/ RMU	
26	Efficacy of Sucralfate in providing post-operativeanalgesia in patients undergoing tonsillectomy	CTU/01/2022/026/ RMU	
27	Efficacy of Clarithromycin verses oral steroids in reducing clinical grade of nasal polyps in preoperative patients of fess.	CTU/01/2022/027/ RMU	
28	Comparison of nasal glucocorticoid, anti- leukotriene vs combination of anti- leukotriene and antihistamine in seasonal allergic rhinitis	CTU/01/2022/028/ RMU	
29	Use of preoperative Tranexamic acid intonsillectomy with or without adenoidectomy to reduce primary hemorrhage	CTU/01/2022/029/ RMU	
Gastroenterology			
30	A prospective observational study combination of proton pump inhibitors with Prokinetics in GERD	CTU/01/2022/030/ RMU	
31	A Prospective Observational Efficacy And Safety Of Dapagliflozin In Patients With NAFLD	CTU/01/2022/031/ RMU	
Infectious Disease			
32	Effectiveness of Ivermectin among covid-19 patients: a randomized controlled trial	CTU/01/2022/032/RMU	

S No	Topic	CTU Regst No	Status
	Medical ICU		
33	Effect of N-Acetyl cysteine therapy on mortality rate in patients of acute aluminum phosphide poisoning	CTU/01/2022/033/ RMU	
	Medicine		
34	To compare the efficacy of single high dose and standard dose vitamin D therapy in painful diabetic neuropathy	CTU/01/2022/034/ RMU	
35	Effect of Hydrocortisone, Thiamine and Acorbic acid on patient admitted with septic shock metabolic resuscitation protocol	CTU/01/2022/035/ RMU	
36	Comparison of effect of Dapagliflozin and Sitagliptin on serum glucose levels, Serum creatinine and GFR as an add an antidiabetic agent in DM type 2 patients with CKD	CTU/01/2022/036/ RMU	
37	Pharmacokinetics Of Loading Dose Of Vitamin D Under Comparison Through Two Different Oral Delivery Methods	CTU/01/2022/037/ RMU	
38	To Compare The Efficacy Single High Dose And Standard Dose Vitamin D3 Therapy In Painful Diabetic Neuropathy	CTU/01/2022/038/ RMU	
39	Comparison Of Effectiveness And Safety Of Rivaroxaban Versus Apixaban In Patients With Deep Venous Thrombosis	CTU/01/2022/039/ RMU	
40	Comparison Of Empagliflozin And Metformin For Improvement In Alanine Amino Transferase And Fatty Liver Index Score In Non-Alcoholic Fatty Liver Disease Patients	CTU/01/2022/040/ RMU	
41	Comparing Efficacy Of Empagliflozin And Dapagliflozin In Type 2 Diabetics.	CTU/01/2022/041/ RMU	

S No	Topic	CTU Regst No	Status
	Gynecology & Obstetrics		
42	A comparison of duration of administration Of prophylactic postpartum magnesium Sulphate	CTU/01/2022/042/ RMU	
43	Comparison of efficacy between high and low dose Aspirin in prevention of pre-eclampsia	CTU/01/2022/043/ RMU	
44	Comparison of induction-labor interval between Prostaglandin e2 pessary and intracervical Foley's catheter in Primigravida	CTU/01/2022/044/ RMU	
45	Comparison of efficacy and Fetomaternal outcomes of Prostaglandin e2 and Misoprostol for IOL in full term pregnancy	CTU/01/2022/045/ MU	
46	Comparison of outcomes of Letrozole combined with Misoprostol versus Misoprostol alone for TOP in patients with delayed miscarriages	CTU/01/2022/046/RMU	
47	To compare the frequency of Neonate mortality and Intraventricular hemorrhage among preterm neonates treated with and without Corticosteroids	CTU/01/2022/047/RMU	
48	Outcome in patients with Gestational thrombocytopenia receiving oral prednisolone versus placebo	CTU/01/2022/048/ RMU	
49	Comparison of efficacy of Clomiphene citrate versus Letrozole in ovulation induction	CTU/01/2022/049/ RMU	
50	Effect of pre-operative single dose of IV dexamethasone on post-operative vomiting in patients undergoing laparoscopic Gynecological procedures	CTU/01/2022/050/ RMU	
51	Frequency Of Metformin-Poor Response And factors Associated With the Need for Insulin As A Complementary Treatment Among The Patients Of Gestational Diabetes Mellitus	CTU/01/2022/051/ RMU	
52	The Efficacy Of Magnesium Sulphate As An Adjunct To Local Anaesthetics for Perineal Pain Relief After Episiotomy	CTU/01/2022/052/ RMU	
53	Comparison Of Therapeutic Serum Magnesium Levels In Intravenous Regimen Vs Intramuscular Regimen Administered To Obese Women With Severe Preeclampsia	CTU/01/2022/053/ RMU	

S No	Topic	CTU Regst No	Status
Ophthalmology (EYE)			
54	Comparison of topical Proparacaine vs Retro bulbar Lignocaine for cataract surgery in terms of patient's satisfaction and pain relief	CTU/01/2022/054/ RMU	
55	Use of topical Insulin to treat refractory corneal ulcer: a comparative study	CTU/01/2022/055/ RMU	
56	Effect of intracameral dexamethasone and its effect on postoperative outcome	CTU/01/2022/056/ RMU	
57	Per-Operative Intra-Cameral Dexamethasone DuringPhacoemulsification And Its Association With Post-Operative Outcome	CTU/01/2022/057/ RMU	
58	Effect Of Subconjunctival Bevacizumab Combine With Fine Needle-Diathermy On Outcome Of Penetrating Keratoplasty In Vascularized Cornea At Holy Family Hospital During 2021 And 2022.	CTU/01/2022/058/ RMU	
Pediatrics'			
59	Use of propranolol versus intralesionalBleomycin in the management of infantile hemangioma	CTU/01/2022/059/ RMU	
60	Comparing efficacy of Imitanib and Nilotinib therapy by determination of side effects and assessment of molecular response in patients of CML	CTU/01/2022/060/ RMU	
61	Carvacrol alleviates hyperuricemia-induced oxidative stress and inflammation by modulating the nlrp3/nf-κb pathway	CTU/01/2022/061/ RMU	
62	Adrenaline And Dexamethasone Versus Adrenaline Alone In Bronchiolitis: A Randomized Controlled Trial	CTU/01/2022/062/ RMU	
63	Comparison Of Prophylactic Vitamin K Administration VS Placebo In Neonates On Prolonged Antibiotics	CTU/01/2022/063/ RMU	
Pharmacology			
64	Estimation of frequency, knowledge and attitude of female sex disorders (FSD) in elderly women and evaluation of topical use of black seed oil & cream and olive oil & cream for Management.	CTU/01/2022/064/ RMU	

S No	Topic	CTU Regst No	Status
65	Determination of beneficial effects of black seed addition with allopathic medicines in mild to moderate hypertensive patients	CTU/01/2022/065/ RMU	1st case report published
66	Clinical studies for the evaluation of black seed oil and gel/cream for the treatment of oral and Vulvo-vaginal candidiasis	CTU/01/2022/066/ RMU	Pilot study completed and accepted for presentation for BPS 2024 meeting , 10-12 december, harrogate UK.
67	Clinical studies for the evaluation of black seed oil and for the treatment of fungal skin infections (tinea or dermatophyte infections)	CTU/01/2022/067/ RMU	Withdraw
68	Comparative metabolic effects of *aloe vera* extracts with Sitagliptin in type 2 diabetes mellitus	CTU/01/2022/068/ RMU	Phase I (initial stage)
Reconstructive Surgery			
69	Comparison of heparin dressing and conventional dressing in second degree burn patients in term of pain relief and wound healing	CTU/01/2022/069/ RMU	
Surgery			
70	Prevention of Seroma formation after MRM by hydrocortisone injection	CTU/01/2022/070/ RMU	
Plastic Surgery			

71	Comparison Of Conventional Dressing Versus Hydrocolloid Dressing For Donor Site After Split Thickness Skin Graft Harvest	CTU/01/2022/071/ RMU	
S No	Topic	CTU Regst No	Status
72	Comparison Of The Outcome Of Wound Healing In Minced Graft Dressing Versus Traditional Paraffin Gauze Dressing At Donor Site After Split Thickness Skin Grafting In Burn Patients.	CTU/01/2022/072/ RMU	
73	Effect Of Oral Supplementation By Vitamin C And Glutathione In Outcomes Of Burn Patients Who Underwent Debridement And Skin Grafting.	CTU/01/2022/073/ RMU	
Cardiology			
74	Comparative Efficacy Of Two-Hour Regimen Of Streptokinase Versus 24-Hour Regimen In Suspected High Risk Or Massive Pulmonary Embolism: i mmediate Clinical And Hemodynamic Outcome	CTU/01/2022/074/ RMU	
Community Medicine			
75	Estimation Of Prevalence, Knowledge And Attitude Of Female Sex Disorders (Fsd) In Elderly Women And Evaluation Of Oral Black Seed (Nigella Sativa) And Topical Black Seed Oil For Management	CTU/01/2022/075/ RMU	

Section IV:

Department Wise Clinical Trials Data: Year 2023

Departmental Clinical Trials Data: Year 2023

S No	Topic	Department	CTU Regst No	Status
Gynecology & Obstetrics				
1	Role Of CoQ10 In Reduction Of Frequency Of Pre-Eclampsia In High Risk Patients	Dr.Touseeef Gynae	CTU/01/2023/001/ R MU	
2	A Comparison Of The Use Of Oxytocin with Oxytocin Plus Misoprostol For Active Management of Third Stage Of Labour In Low Risk Patients After Spontaneous Vaginal Delivery: A Randomized Control Trial	Dr.Zeeshan Ahmed Gyane	CTU/01/2023/003/ R MU	
3	The role of Myoinositol supplementation in the prevention of Gestational diabetes mellitus in high risk pregnant women"	Dr.Saliha Afzal Gynae	CTU/01/2023/006/ R MU	
4	Comparison of Dexamethasone & PG E2 with PG E2 Alone for Successful Induction of Labour and Reduced Duration of Labour	Dr.Anum Gynae	CTU/01/2023/007/ R MU	
Urology				
5	The Efficacy of Tamsulosin versus Combination of Tamsulosin and Solifenacin in the Management of Double-J Stent-Related Lower Urinary Tract Symptoms	Dr.Kamran Urology	CTU/01/2023/002/ R MU	
Paediatrics				
6	The Effect of Oral Vitamin E on Phototherapy Duration in Full Term Neonates with Indirect Hyperbilirubinemia within the First 2 Weeks of Life	Dr.Moazzam Yasin Paediatric medicine	CTU/01/2023/004/ R MU	

S No	Topic	Department	CTU Regst No	Status
7	Effects of Phototherapy on the Serum Magnesium Level in Neonates with Indirect Hyperbilirubinemia	Dr.Aqeela Jabeen Paediatrics	CTU/01/2023/005/R MU	
Cardiology				
8	Comparison between Atorvastatin and Rosuvastatin in Reduction of Inflammatory Biomarkers in Patients with Acute Coronary Syndrome	Dr.Naima Shahzadi Qazi Cardiology	CTU/01/2023/008/R MU	
Anesthesia				
9	"Comparison of Addition of Dexamethasone to Bupivacaine Versus Bupivacaine Alone in Caudal Block for Post-Operative Analgesia in Pediatric Lower Abdominal Surgeries	Dr.Hamza Taveer Anaesthesia	CTU/01/2023/009/R MU	
Gastroenterology				
10	Treatment of Recurrent Aphthous Stomatitis (RAS), Solitary Rectal Ulcers and Hemorrhoids by using low level laser therapy (LLLT) or Photobiomodulation therapy (PBMT)	Dr.Tayyab Gastroenterology	CTU/01/2023/010/R MU	1st case report was published and rest are under process
Gastroenterology				
11	Immunogenicity And Safety of Hepatitis E Vaccine In Chronic Liver Disease Patients	Professor Umer Dr Aqsa (Gastroenterology) 03004064369	CTU/01/2023/012/R MU	Completed December 2024 months because data was completed for 135 patients out of 150 patients
12	Evaluating the Safety and Effectiveness of Sitagliptin and Metformin in Managing Type 2 Diabetes Mellitus in Individuals with Chronic Liver Disease Resulting from Hepatitis C	Dr Saima (Hod medicine) 0333-5169766	CTU/01/2023/013/R MU	Data analysis was completed, and paper is in writing stage

Section V:

Department Wise Clinical Trials Data: Year 2024

Departmental Clinical Trials Data: Year 2024

S No	Topic	Principal investigator	CTU Regst No	Status
1	Diagnostic yield of Broncho alveolar lavage GeneXpert in Sputum-scarce and Smear-negative Patients with Suspected Pulmonary Tuberculosis in RTH Rawalpindi	Dr.Khalida Asghar (Resident MD-Medicine) 03328480856	CTU/07/2024/001/RM U	Waiting for BASAR
2	Title of Research Synopsis: Efficacy between "Adenoidectomy with Myringotomy" VERSUS "Adenoidectomy with Grommet Insertion" in management of Otitis Media with Effusion in terms of hearing improvement; A Randomized controlled trial at RMU Allied Hospitals	Dr Mahnoor Anwar (Resident MS - ENT)	CTU/07/2024/002/RM U	Waiting for BASAR
3	Comparison between fisher and modified fisher technique in unilateral cleft lip and cleft lip palate	Dr. Fahad Abid (MS Plastic and reconstructive surgery) 0316-5757254	CTU/07/2024/003/RM U	Data collection
4	Comparison of efficacy of hydrocortisone with salbutamol versus dexamethasone with salbutamol in acute severe exacerbation of asthma in children	Dr Ayesha Shahbaz (MD-Pediatrics)	CTU/07/2024/004/RM U	Sampling
5	A Comparative Study of Desarda's Versus Lichtenstein's	Dr Fareeba (PGT Surgery	CTU/07/2024/005/RM U	Waiting for BASAR

S No	Topic	Principal investigator	CTU Regst No	Status
	Repair for Inguinal Hernia, A single centered trial			
6	Pilot study synopsis: Application of am- tPRNS in parkinsons's disease	Dr Waqas Ahmad and Dr Arafat 0323-8455254 (Comsat University)	CTU/07/2024/006/RM U	ERB approved and waiting for approval from DRAP
7	Comparing the Effect of 4% Lidocaine Infused Polymyxin Nasal Packs vs Only Polymyxin Nasal Packs on Postoperative Pain in Patients Undergoing Septoplasty	Dr. Javeria Awan (University Resident MS ENT) 0335 9968235.	CTU/07/2024/007/RM U	Waiting for BASAR
8	A randomized control trial assessing the efficacy of nasal steroids with antibiotics in the reduction of adenoid hypertrophy symptoms	Dr. Maimoona Maheen (Postgraduate resident MS otorhinolaryngolog y department of otorhinolaryngolog y) BBH	CTU/07/2024/008/RM U	Waiting for BASAR
9	Effect of feedback on reflection, on deep learning of undergraduate medical students in a clinical setting	Dr Zainab Maqsood (Gynaecology & Obstetrics) SR. Registrar HFH 03341050551	CTU/07/2024/009/RM U	Paper was submitt ed for publicat ion
10	Effectiveness of per operative irrigation using normal saline in prevention of	DR. Anwaar Ul Mustafa	CTU/07/2024/010/RM U	Sampling

S No	Topic	Principal investigator	CTU Regst No	Status
	surgical site infections in compound skull fractures	(MS Neurosurgery) 0334-6366621		
11	Efficacy of Upper Limb Orthosis in Pregnant Women Presenting with Carpal Tunnel Syndrome	Aimen Shahbaz (Orthotics and Prosthetics) 0332-5996333	CTU/07/2024/011 /RM U	Completed
12	Efficacy of Ultrasound-Guided Foam Sclerotherapy Vs Open Surgery in the Treatment of Varicose Veins”	Dr. Arooj Zahra (General Surgery - MS) Department of general RTH	CTU/07/2024/012 /RM U	Waiting for BASAR
13	Comparison of effect of infusion vs bolus administration of tranexamic acid in blood loss and transfusion requirements in craniotomies greater than 3cm	Dr. Farkhanda Batool (Postgraduate Trainee MS- neurosurgery) 0334-5379118	CTU/08/2024/013 /RM U	Waiting for BASAR
14	Study Proposal Synopsis Adalimumab (Dalimab®) Searle Pharmaceutical industry	Dr Tayyab Dr Aqsa (0303-6661586) (0333-0940785)	CTU/08/2024/014 /RM U	Send to principa l investig ator for further suggesti ons

S No	Topic	Principal investigator	CTU Regst No	Status
15	Efficacy of vibrational Anesthesia on Pain Experienced during Digital and Wrist Block; Design: Quasi- Experimental Setting: Emergency Department of Holy Family Hospital	Dr Maryam Ghani PGR Department of Plastic Surgery Holy Family Hospital Rawalpindi	CTU/08/2024/015 /R MU	Waiting for Basar points
16	A Comparison of Kangro mother care verses routine care on body temperature and early initiation of breast feeding in neonates.	Dr. Sobia (assistant Professor HFH, Gynecology)	CTU/010/2024/01 6/ RMU	In-process
17	A comparative study of efficacy of 0.03% tacrolimus eye ointment and 0.05% cyclosporin eye drops in the treatment of vernal keratoconjunctivitis	Dr Munaza (post graduate trainee, deptt. Of ophthalmology BBH) 03125477796	CTU/012/2024/01 7/ RMU	Waiting for BASAR
18	Clinical efficacy of low dose aspirin VSLOW Dose plus calcium supplementation in prevention of preeclampsia	Dr Maryam younes FCPS-II, Deptt of Gynecology, BBH 0301-4452876	CTU/012/2024/01 8/ RMU	Waiting for BASAR
19	Comparison of metformin verses combination of metformin with myoinositol for menstrual irregularities in polycystic ovarian syndrome (PCOS).	Dr sofia noureen (post graduate trainee, Deptt of Gynecology, BBH) 0333-6658115	CTU/012/2024/01 9/ RMU	Samplin g
20				

Title:

Immunogenicity and Safety of Hepatitis E Vaccine in Chronic Liver Disease Patients

Pi: Prof. Dr. Muhammad Umar, Dr Aqsa, CTU # CTU/01/2023/012/RMU

Summary

This clinical trial aims to evaluate the immunogenicity and safety of the hepatitis E vaccine (HECOLIN) in patients with chronic liver disease (CLD). The study is being conducted at the Centre for Liver and Digestive Diseases, Holy Family Hospital, Rawalpindi, over two to three years with a sample size of 150. It includes adult patients with radiological / biochemical evidence of CLD who will receive the vaccine in three doses at 0, 1, and 6 months. The study will monitor anti-HEV IgG levels and document adverse effects to compare outcomes between CLD patients and those with chronic viral hepatitis B and C. The ultimate goal is to reduce acute-on-chronic liver failure and mortality in CLD patients. So far 135 patients have been enrolled and we aim to achieve our target in next 2 months. Once enrollment is completed, the study would be completed in next 8 to 10 months.

Effect of Low-Level Laser Therapy/ Photobiomodulation Therapy on Solitary Rectal Ulcers

PI:
Dr. Muhammad Saleem, Deputy Chief Scientist
National Institute of Lasers and Optronics College, Pakistan Institute of Engineering and Applied Sciences
Collaborators/Co-PI:
1. Prof. Dr. Hamama-Tul-Bushra, FCRS, RRCP, FRCP
2. Dr. Tayyab Saeed Akhter, FCPS
Department of Gastroenterology, Holy Family Hospital, Rawalpindi Medical University

HEC NRPU Research Project-14617
Development of laser systems and light delivery probes for treating oncological and non-oncological disease conditions through photodynamic therapy and Photobiomodulation therapy

Institutional Research & Ethics Review: 309/IREF\RMU\2022 CTU/01/2023/010/RMU Registered with ORIC RMU

Photobiomodulation(PMBT)– Low Level Laser Therapy

- Light (600-1000 nm) enters the cell mitochondria and is absorbed by chromophores (cytochrome C oxidase) which then increases its activity.
- It also enhances other mitochondrial products such as NADH, protein, and RNA as well as the oxygen consumption.
- The resulting transcription phenomenon assist bio-modulation.

- **Adenosine triphosphate (ATP)**
- **Reactive oxygen species (ROS)**
- **Nitric oxide (NO)**

HYPOTHESIS:

- PBMT assists in the rapid healing of solitary rectal ulcers by reducing ulcer size and severity.

Study design:

Randomized open-labelled control study with two treatment groups

- **Group A:** Intervention group (who will receive laser therapy in addition to standard management)
- **Group B:** Control group(standard treatment group)

Sample Size:

40


Mary Ann Liebert, Inc. publishers
Effective Treatment of Solitary Rectal Ulcer Syndrome by Using Photobiomodulation Therapy: A Case Report
Abstract
Golden Jubilee Celebrations
6th RMU International Scientific Conference
17-23 Dec, 2023
Effective treatment of solitary rectal ulcer by using Photobiomodulation therapy as an innovative modality: A case report
Introduction:
Case Report:
Conclusion
Rawalpindi Medical University

Efficacy of Upper Limb Orthosis in Pregnant Women Presenting with Carpal Tunnel Syndrome

Aimen Shahbaz[1], Amir Nawaz Khan[2], Obaid -Ur-Rehman[3], Warda Sarwar[4], Ajla Javaid[5]

Abstract

Objective: To find the efficacy of orthosis on the symptoms of CTS in pregnant women and to investigate the impact of use of CTS splint on symptom relief in pregnant women with CTS.

Methods: A randomized controlled trial (RCT) was conducted involving 28 pregnant women diagnosed with CTS. Fourteen participants were assigned to the intervention group, receiving upper limb orthosis for four weeks, while the remaining 14 comprised the control group. Outcome measures were assessed using the Modified Boston Questionnaire (MBQ), focusing on symptoms such as tingling, numbness, discomfort task difficulty and weakness.

Results: Before the intervention, the distribution of patients based on symptom severity according to the Modified Boston Questionnaire (MBQ) showe d that 85.7% experienced numbness or tingling, 71.4% reported pain or discomfort, 78.6% woke up at night due to symptoms, and 100% had difficulty grasping small objects, difficulty with activities, and weakness in hands or fingers. After the intervention, the intervention group demonstrated a significant reduction in MBQ scores (96.5%) and symptoms (92.9%), compared to the control group (3.5% and 7.1%, respectively). The t-test analysis revealed a significant difference ($p < .001$) between the intervention and control groups, indicating the efficacy of upper limb orthosis in pregnant women presenting with CTS.

Conclusion: The study demonstrates the effectiveness of upper limb orthosis in reducing symptoms of carpal tunnel syndrome (CTS) among pregnant women . With a significant reduction in MBQ scores and symptoms severity observed in the intervention group compared to control over a four -week period, early intervention with orthosis proves beneficial. These findings tell the importance of timely diagnosis an d conservative management in alleviating CTS symptoms during pregnancy, potentially minimizing the need for more invasive interventions.

Keywords: Carpal Tunnel Syndrome, Pregnancy, PRCTS, Wrist Splint, Upper limb orthosis, Median Nerve.

[1,2,3,4,5] Department of Orthopedics, BBH, Rawalpindi, Pakistan

1. Introduction

Carpal tunnel syndrome is a compression neuropathy of median nerve that causes numbness, tingling and pain in the distribution of the median nerve (thumb, index, middle finger, and the radial side of the ring finger.[1-4] It occurs when the median nerve is squeezed or compressed as it travels through the wrist.[2,3] The carpal tunnel is a narrow passageway surrounded by bones and ligaments on the palm side of the hand[1] The carpal tunnel is a nonextendible osteo fibrous tunnel defined as the space located between the flexor retinaculum, which forms the roof, and the carpal sulcus, which forms the base.[6] The anatomy of the wrist, health problems, and repetitive hand motions can contribute to carpal tunnel syndrome.[1,5] A figure of 55–65% of CTS cases are present bilaterally.[1] Pressure on the nerve can happen several ways, including: • Swelling of the lining of the flexor tendons, called tenosynovitis. • Joint dislocations • Fractures • Arthritis • Fluid retention during pregnancy. These conditions can narrow the carpal tunnel or cause swelling in the tunnel. Thyroid conditions, rheumatoid arthritis and diabetes can also be associated with carpal tunnel syndrome. There can be many causes of this condition.[15]

Carpal tunnel syndrome (CTS) is a common problem in pregnancy. Various theories, including morphological factors,[7] hormonal changes[8] and fluid retention,[9,10] have been suggested as contributing factors of CTS in pregnancy. CTS occurs most frequently during the third trimester of pregnancy and a majority of women have symptoms that are severe enough to affect hand function and sleep,[11] indicating that quality of life is significantly affected in these patients. Various factors, such as an increase in body mass index (BMI), hormones, fluid redistribution, and maternal age, are involved in the etiology of PRCTS.[12,13] Symptoms of this condition can include pain, numbness, tingling, occasional clumsiness, tendency to drop things. The numbness or tingling most often takes place in the thumb, index, middle and ring fingers. The symptoms usually are felt during the night but may also be noticed during daily activities such as driving or reading a newspaper. In severe cases, sensation and strength may be permanently lost.

Diagnosis of Carpal Tunnel Syndrome can be obtained by an accurate patient history or by performing physical examination that may include assessing personal characteristics, conducting a sensory examination, performing manual muscle testing of the upper extremity, and utilizing provocative and/or

Future prospective of RMU-CTU

The future prospects of a Clinical Trial Unit (CTU) at Rawalpindi Medical University (RMU) are promising, given the growing emphasis on evidence-based medicine, advancements in healthcare, and Pakistan's increasing participation in global clinical research. The worthy Vice Chancellor (VC) of Rawalpindi Medical University (RMU), overseeing the Clinical Trial Unit (CTU) would be a critical component of a broader vision to position the university as a leader in clinical research and medical innovation. Below are some strategic future plans you can pursue:

1. Establish RMU as a Research Hub

Create an RMU Research Institute that integrates the CTU, other research departments, and centers of excellence. Invest in modern infrastructure with dedicated space for trial activities, b, data analysis, and training.

2. Policy and Governance:

Formulate policies that support ethical and efficient clinical trial operations aligned with national and international standards. Establish a high-level advisory board of clinical research experts to guide CTU operations and strategy.

3. Faculty Development:

Launch advanced training and certification programs for faculty, staff, and students in clinical research methodologies, ethics, and management. Provide seed grants to faculty members for initiating innovative pilot studies.

4. National and International Collaborations:

- **Collaborate with Government Agencies**: Partner with the Drug Regulatory Authority of Pakistan (DRAP) to streamline clinical trial approval processes.
- **Global Partnerships**: Engage with international universities, pharmaceutical companies, and Contract Research Organizations (CROs) for collaborative trials and capacity building.

5. Academic Integration:

- **Curriculum Enhancement**: Incorporate clinical research modules into MBBS, nursing, and postgraduate programs to foster a research culture.
- **Dual-Degree Programs**: Introduce combined degrees such as MD-PhD or MPH-PhD to encourage research-oriented careers.

6. Focus on Priority Health Issues:

- **Target Local Health Challenges**: Prioritize research on diseases prevalent in Pakistan, such as infectious diseases, non-communicable diseases, and maternal-child health issues.
- **Innovative Studies**: Promote research in cutting-edge fields like personalized medicine, genomics, and digital health.

7. Ethical and Regulatory Leadership:

- **Strengthen IRB/EC**: Ensure the Institutional Review Board/Ethics Committee operates transparently and efficiently.
- **Accreditations and Certifications**: Seek international certifications like AAHRPP or ISO for the CTU.

8. Public Engagement and Awareness:

- **Community Education**: Conduct campaigns to inform the public about clinical trials and their benefits.
- **Patient-Centered Approach**: Ensure trials focus on improving patient outcomes and address their needs.

The CTU at RMU holds the potential to become a cornerstone of innovation and excellence in medical research, driving improvements in healthcare at both the national and international levels. With strategic investment and leadership, it can make transformative contributions to science and society.