Faculty of Medicine
Institutional Review Board (IRB)

Research Proposal Form

This section is for Official Use Only

Reference Code:

Date of application (dd/mm/yyyy):

This section is for the applicant to fill.

- Use **Times New Romans** Font, **size 11** and adjust **line spacing to 1.5** all through the application form
- **Do not** CAPITALIZE all words

Part 1: General

Master Degree ■ **b. MD** ☐ **c. Independent Research/Project** ☐

1.1 Applicant Name (responsible for all correspondences and accuracy of data)**:** **Maikel Merit Gerges Morkos**	**Department:** General surgery
e-mail address: Michael.16266363@med.aun.edu.eg	**Mobile Phone: 01271267725**
الاسم باللغة العربية :مايكل مريت جرجس مرقس	**Home Phone: 01091018115**

1.2 English Title of research project:

Role of Platelet Rich Plasma in Bone regeneration after enucleation of odontogenic jaw cysts

1.3 Arabic Title (use the WHO Unified Medical Dictionary)**:** www.emro.who.int/unified-medical -dictionary.html

دور البلازما الغنية بالصفائح الدموية فى تجديد العظام بعد أستئصال الاكياس الفكية السنية.

1.4 Do you need funding from Assiut Medical School Grants Office?

Yes ☐ No ■

Mention other sponsoring agent(s) if any: ……...

Part 2: Research Details

2.1 Background (Research Question, Available Data from the literature, Current strategy for dealing with the problem, Rationale of the research that paves the way to the aim(s) of the work). **(200-250 words max.)**

Jaw cysts are common lesions in the oral and maxillofacial region. Enucleation of cyst wall & curettage has evolved as the treatment of choice. In order to reduce infections and to accelerate bone regeneration, by using of Platelet rich plasma.

Platelets are involved in regeneration at sites of pathology, apart from their role in clotting. A preparation composed mainly of platelets (platelet-rich plasma gel)

applied to sites of bony pathology, after surgical treatment of lesions, may hasten bone regeneration.

An interesting idea developed that the addition of a concentrate of platelets, to wounded tissues or surgical sites, may enhance the body's natural wound healing mechanisms [1]. Platelet-rich plasma (PRP) is the accepted term to describe the preparation made out of autologous platelets suspended in autologous plasma, in concentration greater than normally found in peripheral blood

Because it is autologous, PRP avoids the risk of transmissible diseases such as HIV, Hepatitis B, C or D and other blood-borne pathogens [2]. A clot accelerator such as bovine thrombin is added to gel the PRP or PRP is added to other materials such as collagen, gelfoam, etc.

2.2 Aim(s) of the Research (50 words max):

in the present study, the effect of PRP on bone regeneration when applied to the site of removal of cyst of the jaws is evaluated. PRP was delivered to the site combined with gelfoam. Thrombin clot accelerator was not used.

2.3 Research Domain (Faculty Research Plan). ☐

1. **Trauma**; epidemiology, prevention, management, and rehabilitation
2. **Communicable diseases**; prevention, screening for early detection, and management
3. **Infection** control and health-care-associated infections and Safety of medical service providers
4. **Population** problem, maternal and perinatal morbidity and mortality
5. **Non-communicable diseases**; prevention, screening for early detection, and management
6. **Evidence based management** of common medical and surgical problems
7. **Organ Transplantation**
8. **Geriatric Health**; promotive, preventive, curative and rehabilitative services
9. **Stem cells and/or tissue culture** application in managing various diseases in clinical trials
10. **Experimental Research;** basic and animal model research that may lead to possible enhancement in health services
11. Others, clarify,----------

2.4. Research Methods and techniques:

2.4.1- **Type of the study:** interventional, prospective clinical trials

2.4. 2- **Study Setting:** general surgery department , Assiut university , in the period from 10/2024 to 10/2026

2.4. 3- **Study subjects:**

a. Inclusion criteria:

1. All patients admitted to AUH with mandibular or maxillary Odontogenic cysts
2. Size of the cyst more than 2 cm
3. The lesion could be visualized radiographically
4. Patients within the age range of 20 to 50 years

b. Exclusion criteria:

1-Neoblatic lesions

2- Patients who were alcoholics & smokers

3-Patients with systemic diseases

4-History of bleeding tendencies, blood dyscrasia

5-Low platelet count

6- Patients unable or unwilling to return for follow-up

c. Sample Size Calculation: The sample size was calculated using G*power software 3.1.9.4., the minimum required sample size is 42 patients (21 in each group)

based on the

following assumptions:

The main outcome variable is the role of Platelet Rich Plasma in Bone regeneration after enucleation of odontogenic jaw cysts. Based on previous study (Evaluating the Efficacy of Platelet-Rich Plasma (PRP) in Accelerating Healing and Reducing Complications in Oral Surgery) we expect to find large effect size = 1.164

The main statistical test is t-test to detect the difference between the two groups.

Two tailed

Alpha = 0.05

Power = 0.95

Effect size = 1.164

Allocation ratio= 1

The Parameters :

Mean ± SD of The alveolar bone density in PRP

patients at 6 months postoperative : 141.13±10.81

Mean ± SD of control group at 6 months postoperative : 127.91±11.87

2.4.4 –**Study tools (in detail, e.g., lab methods, instruments, steps, chemicals, …):**

- **Patient history**

  history of tooth extraction

  pain in jaw

- **Examination**

  jaw or maxillary swelling

- **Laboratory investigation**

  Complete blood picture

  Coagulation profile

  Kidney function

  Liver function

- **Imaging**

  panorama xray

  CT teeth

- **Instruments & method**

  Preparation of PRP

Preoperatively, platelet-rich plasma was prepared in the Haematology Laboratory from 20 ml of the patient′s blood using an R8-C Laboratory Centrifuge (Remi Motors Ltd., Mumbai) using an aseptic technique.

Armamentarium

Anticoagulant citrate phosphate dextrose, sterile 10 ml test tubes (2 nos.), sterile pipette, Vacutainer tubes 5 ml (2 nos.), 10 ml syringe and 21 gauge needle were used.

Procedure

Twenty millilitres of venous blood is collected from antecubital region with a 20- ml syringe and transferred to two test tubes containing 1.4 ml anticoagulant (citrate phosphate dextrose solution) each. (A ratio of 1.4 ml of anticoagulant to 10 ml of blood) It is then centrifuged for 10 min at 1,300 rpm. The result is a separation of whole blood into a lower red blood cell region and an upper straw colored plasma region

Surgical procedure

The enucleation of cyst or tumour and any further treatment to eliminate pathology was performed nder local anesthesia, or in case of large lesions, treatment was performed under general anesthesia. Affected teeth were either removed or treated endodontically.

In the study group, for Mlling the bony defect PRP gel was used. At the time of application, 1 ml of 10 % calcium gluconate was added to the PRP and mixed well. A small cube of Gelfoam was added to the test tube to soak load PRP (Fig. 4). The test tube

was left standing for 5 min. A gel formed that was placed inside the defect . Primary wound closure was performed.

Postoperative follow-up : after one month, three months & six months

2.4.5 –**Research outcome measures:**

a. Primary (main):

1 infection

2.bone healing

b. Secondary (subsidiary):

1 operation time

2 hospitalization time

3 Recurrence

2.5-Data management and analysis (Details needed):

Data collection : data will be collected in patient sheet.
Computer software : Microsoft Office, SPSS statistical program
Statistical tests :: Data will be managed by Microsoft Excel, Statistical analysis of the data will be Performed using SPSS_22 software package, Data will be presented in the form of frequency and percent, Studied groups will be evaluated by analysis of variances.

2.6-References (max. 15) and written in Vancouver style:

1. Doiphode AM, Hegde P, Mahindra U, Santhosh Kumar SM, Tenglikar PD, Tripathi V. Evaluation of the efficacy of platelet-rich plasma and platelet-rich fibrin in alveolar defects after removal of impacted bilateral mandibular third molars. J Int Soc Prevent Communit Dent 2016;6:S47-52.
2. Hanif M, Sheikh MA. Efficacy of platelet rich plasma (PRP) on mouth opening and pain after surgical extraction of mandibular third molars. J Oral Med Oral Surg 2021;27:9.
3. Tiwari A, Gupta N, Singla D, Swain JR, Gupta R, Mehta D, et al. Artificial intelligence's use in the diagnosis of mouth ulcers: A systematic review. Cureus 2023;15:e45187. doi: 10.7759/cureus.45187.
4. Intini G. The use of plateletrich plasma in bone reconstruction therapy. Biomaterials 2009;30:4956-66.

5. Tiwari A. A traumatic ulcer caused by accidental lip biting following topical anesthesia: A case report. Cureus 2023;15:ee38316. doi: 10.7759/cureus.38316.
6. Dohan DM, Choukroun J, Diss A, Dohan SL, Dohan AJ, Mouhyi J, et al. Plateletrich fibrin (PRF): A secondgeneration platelet concentrate. Part I: Technological concepts and evolution. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2006;101:e37-44.
7. Tiwari A, Kumar A, Jain S, Dhull KS, Sajjanar A, Puthenkandathil R, et al. Implications of ChatGPT in public health dentistry: A systematic review. Cureus 2023;15:e40367. doi: 10.7759/cureus.40367.
8. Rathore A, Tiwari A, Nazim M, Gupta AK, Gande M, Krishnakumar J. Detection of human papillomavirus and its association with potentially malignant disorders and oral squamous cell carcinoma: A retrospective study. J Pharm Bioallied Sci 2022;14(Suppl 1):S820-4.
9. Kulkarni MR, Thomas BS, Varghese JM, Bhat GS. Plateletrich fibrin as an adjunct to palatal wound healing after harvesting a free gingival graft: A case series. J Indian Soc Periodontol 2014;18:399-402.

Part 3: Ethical Considerations *(Written in detail taking into consideration the items below):*

3.1. Risk – benefit assessment:

As the study is observational, there are no additional risks to the patients other than the recognized risks of their standard care.

3.2. Confidentiality (dealing with data and data dissemination should be confidential).

The confidentiality of all participants admitted to this study will be protected to the fullest extent possible. The study participants will not be identified by name in any report or publication resulting from data collected in this study.

3.3. Statement describing the research procedure to be given to the participants.

Ethical aspects whether substantial or procedural will be implicated in this study. Before participants are admitted in this study, the purpose and nature of the study as well as the risks will be explained to their parents. The participants and/or their parents must agree that he/she understands the investigational nature of the study, its inherent risks and benefits, his/her rights to terminate participation in this study without affecting his/her rights in having proper health care in the study site, whom to contact with questions regarding the study and that he/she is freely given an informed consent to participate in this study

3.4. Informed consent.

Informed written or oral consent of the patients will be acquired before participation in the study.

3.5. Other ethical concerns:

- The research should be conducted only by scientifically qualified and trained personnel.
- The research should be based on relevant pre-clinical investigations in animals.
- **The detailed consent form must be inserted here in the proposal.**

إقرار بالموافقة على المشاركة فى البحث.

أقر انا .....

بانني اطلعت على بيان مفصل عن البحث المقدم من الطبيب ط م /مايكل مريت جرجس مرقس

وانه قد تم اطلاعى على الهدف من هذه الدراسة واستراتيجية الدراسة كاملة كما وردت فى استراتيجية البحث مع ذكر احتمالات المتاعب التى قد يرد حدوثها من الدراسة وانه سوف لا يترتب على عدم موافقتى على الاشتراك فى البحث حجب اى خدمة طبيه عنى

لقد قرات المعلومات السابقة او قرئت علىا وكانت لى الفرصة السؤال عما اريد وتم اجابة اسئلتى جميعها وبما ارضانى

واوافق بكامل اختياري على المشاركة فى هذه الدراسة و افهم انه من حقى التوقف عن المشاركة فيها في اى وقت لاحق دون أن يؤثر ذلك على الخدمة الكلية المقدمه لى

توقيع المريض المشارك فى البحث .....

العنوان .....

التاريخ .....

Part 4: Funding (Mandatory for those requesting funding from Grant Office)

4.1. Total funds requested:	**LE**

4.2. Author responsible for managing the budget/grant (Cannot be a resident):			
Name			
Department			
e-mail		**Mobile**	

4.3. Budget Details	**Cost**
▪ Research equipment and accessories	
▪ Chemicals/Medications	
▪ Data entry	
▪ Statistical analysis	

4.4. All researchers' <u>International publications</u> in the last 3 years.

	Title	**Journal**	**Impact Factor**
1			
2			
3			
4			

5			

(Add others if required)

4.5. Details of Previously Obtained Grants (institutional or others):

	Title	Name of Applicant for grant	Date obtained	Finished Yes/No	Published Yes/No
1					
2					
3					
4					

(Add others if required)

4.6. Research reporting timetable (Mandatory if applying for a fund):

Activity ***(Other activities may be added)***	***Time required (Months)***											
	2	**4**	**6**	**8**	**10**	**12**	**14**	**16**	**18**	**20**	**22**	**24**
Preparation and development of Material												
Training of personnel involved in the research (if needed)												
Research work (Clinical, lab work or field work)												
Data entry and analysis												
Research writing												
Publication												

**** Numbers indicates the time in months needed to complete each part of the project.***
**** Please half squares corresponding to time required for each specific action***

يتعهد الباحثون بنشر نتائج البحث الممول من وحدة تمويل الأبحاث فى إحدى الدوريات العلمية المحكمة والمدرجة على قاعدة **Scopus** أو **Web Of Science** فى خلال الفترة الزمنية المحددة فى البند السابق من قبلهم والا يتم خصم مبلغ التمويل من مرتباتهم بالتساوى فيما بينهم كما يتعهدوا بالإشارة الى مساهمة وحدة تمويل الأبحاث بكلية طب أسيوط عند نشر البحث.

Part 5 – Declaration (Name in printed letters):

I / we (all investigators) certify that, to the best of our knowledge and after reasonable inquiry, the information contained in this application, and any supporting documents provided with this application, are **correct and complete**, and that this research has not been conducted or published before.

يتعهد الباحثون بنشر نتائج البحث الممول من وحدة تمويل الأبحاث فى إحدى الدوريات العلمية المحكمة والمدرجة على قاعدة **Scopus** أو **Web Of Science** فى خلال الفترة الزمنية المحددة فى البند السابق من قبلهم والا يتم خصم مبلغ التمويل من مرتباتهم بالتساوى فيما بينهم كما يتعهدوا بالإشارة الى مساهمة وحدة تمويل الأبحاث بكلية طب أسيوط عند نشر البحث.

Authorship Responsibility (Add more authors if required)							
	Title	**Name**	**Role****	**e-mail**	**Phone**	**Department**	**Signature**
1	Prof	Samy Mohamed Osman Masoud	1.1 2.2 3.4	samyosman@aun.edu.eg	01001519642	General surgery	
2	Prof	Diaa El-Din Saber Ahmed	1.3 2.1 3.1	dr.diaasaber@gmail.com	01007967946	General surgery	
3	Prof	Ahmed Abdo Gad Yousuf	1.2 2.2 3.3	ahmeddeek2020@aun.edu.eg	01097104550	General surgery	
4	Resident	Maikel Merit Gerges Morkos	1.2 2.1 3.1	Michael.16266363@med.aun.edu.eg	01271267725	General surgery	
5							

****Choose at least 1 from each of the 3 groups below**

Group 1	Group 2	Group 3
1.1- Conception and design 1.2- Acquisition of data 1.3- Analysis and interpretation of data	2.1- Drafting of the submitted protocol 2.2-Critical revision of the submitted protocol for important intellectual content	3.1- Statistical analysis 3.2- Obtaining funding 3.3- Administrative, technical, or material support 3.4- Supervision 3.5- Other (specify)

After completing the application form, please

1. Record the completed and revised application form on a **CD** and present to the Vice Dean Research Office.
2. **All authors should sign a printed copy** of the completed application form that should be presented as well to the Vice Dean Research Office.
3. A **copy** of the printed and signed research application form should be presented to the **Ethical Committee**.
4. It is the applicant responsibility to make sure that the application form is fully and accurately completed and that all other supporting documents or formalities are completed in due time.