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):

10/08/2023

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)**:**	**Department:**
Ahmed Dify Kamal Mohamed	**General Surgery**
e-mail address: ahmeddify94@gmail.com	**Mobile Phone: 01022552241**
الاسم باللغة العربية: أحمد ضيفي كمال محمد	**Home Phone:** .....

1.2 English Title of research project:

Evaluation of Rhomboid flap outcome in the surgical treatment of recurrent sacrococcygeal pilonidal sinus vs. Deep suturing

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

تقييم نتائج السديلة المعينية في العلاج الجراحي للناسور العصعصي المتكرر مقابل الخياطة العميقة

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.)**

Pilonidal disease derives its name from Latin- pilus meaning "hair," and nidus meaning "nest" **(1)**. The source of pilonidal disease is thought to be a deep intergluteal sulcus. It is widely accepted that the establishment of the pilonidal sinus results from the penetration of shed hair shafts through the skin, which ultimately leads to an acute or chronic infected site **(2)**.

Pilonidal disease is largely considered a surgical disease, especially in acute instances with secondary infection and abscess. Infection or abscess requires incision and drainage. Definitive treatment is delayed the majority of the time if there is an acute infection or abscess until after the infection has been addressed. Surgical options for chronic disease are numerous and can include "pit picking," curettage, aspiration, unroofing, or surgical excision. Defects can be closed primarily, with flaps or grafts, or allowed to heal by secondary intention **(3-5)**.

The most serious problem of the various surgical approaches proposed is the recurrence rate, ranging from 0% to 40% **(6, 7)**.

The surgical treatment of patients with recurrent disease does not differ from the surgical treatment of primary pilonidal disease. In case of a recurrence with an abscess, incision and drainage prevail, while in case of chronic recurrent disease, a flap based procedure may be indicated following sinus excision with scarring, like the rhomboid flap **(8, 9)**.

To the best of our knowledge, the existing literature is poor with studies comparing flap-based techniques with deep suturing (or primary closure) techniques in the management of recurrent pilonidal disease.

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

This prospective clinical trial aims to compare the perioperative outcomes of rhomboid flap versus deep suturing in the management of recurrent sacrococcygeal pilonidal disease.

2.3 Research Domain (Faculty Research Plan).

Evidence-based management of a common surgical problem.

2.4. Research Methods and techniques:

2.4.1- **Type of the study:** A randomized controlled Clinical Trial

2.4. 2- **Study Setting:** General Surgery Department, Assiut University Hospitals.

2.4. 3- **Study subjects:**

a. Inclusion criteria:

b. Adult patients aged between 18 and 60 years;

c. Patients with one or two small inactive sinuses will be included for easier excisional procedures;

d. Previous intervention for pilonidal disease whether surgical or non-surgical;

b. Exclusion criteria:

1- Patients with an acute abscess.

2- Patients with mall inactive pilonidal sinus disease.

3- Age beyond the previous limits.

4- Patients with primary pilonidal disease.

5- Refusal to participate in the study.

6- Unfit for anaesthesia and surgery.

7- Patients with malignant neoplasms or inflammatory bowel disease.

c. Sample Size Calculation:

The required sample size was calculated using the IBM[a] SPSS[a] Sample Power[a] version 3.0.1 (IBM[a] Corp., Armonk, NY, USA). A previous study conducted by Cihan et al. reported that the incidence of recurrence after Rhomboid Flap was 5.71% **(9)**. Thus, it was estimated that a minimal sample size of **32 patients** is required to achieve a power of 80% to detect expected difference of 14 % in the incidence of recurrence, at a significance level of 0.05. An equal number will be recruited in the deep closure group.

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

All patients will be subjected to complete history taking (focusing on the duration since the primary operation, symptoms and its duration), thorough physical examination, and routine preoperative blood tests (CBC, renal function, liver function, prothrombin time, random blood glucose). Additionally, conventional or magnetic resonance sinogram will ordered when required.

The rhomboid flap Approach (32 patients)

The patient will be operated on under spinal anesthesia. The patients will be placed in prone jack-knife position on the operating table with the legs slightly abducted and the buttocks strapped apart by adhesive tapes. The anus will be excluded from the operative field by surgical drapes. The pathologic area to be excised will be marked. This area will be

enclosed by a rhombus shape with the long axis in the midline (ABCD). Lines AB = BC = CD = DA will be equal to each other, with the axis AC being along the natal cleft. Line BD will be extended transversely and then the line EF will be drawn equal in length. The rhombus containing the pilonidal sinus will be then excised down to the periosteum in the midline and gluteal fascia laterally. Meticulous hemostasis will be done by means of electrocautery.

The flap will be dissected deep to the gluteal fascia (subfascial level) so as to raise thick a fasciocutaneous flap. This will assure good vascularity of the flap without dead space. The rhomboid flap (CDEF) will be mobilized from the gluteal fascia and sutured without tension in three layers (gluteal fascia with 2/0 Vicryl, subcutaneous fat with 3/0 Vicryl, and the skin with 4/0 Prolene). As all sides will be equal in length, the flap fits in place without tension. A suction drain will be left behind and the wound will be dressed as usual. Pressure wound dressing will be applied and removed on the third postoperative day.

The deep suturing approach (32 patients)

A vertical elliptical incision encompassing all pilonidal pits will be made and excision of the sinus will be carried out down to the level of the sacrococcygeal fascia. Tension will be released by a limited sharp dissection above the fascia. After haemostasis is ensured using electrocautery, a suction drain will be inserted through a separate incision, then the deep fascia will be approximated and the wound will be closed in layers using polyglactin 0 sutures. Finally, the skin will be closed with 2/0 polypropylene interrupted mattress sutures.

Postoperative care and follow-up

Standard postoperative care, including mobilization and return to normal diet as quickly as possible will be recommended. Early postoperative complications (bleeding and urine retention) will be noticed and recorded. Pain score and early wound infection will be recorded. Post-operative pain will be assessed on the first, fourth postoperative day and at stitch removal using a visual analogue scale (VAS) from zero (no pain) to 10 (worst pain imaginable) **(10)**.

Patient will be discharged usually on the next day. Oral antibiotics and analgesics will be prescribed on patient's discharge. All the patients will be advised to shave the area around the operative site at least monthly.

All the patients will be recommended to visit the outpatient clinic twice weekly for two weeks then weekly for another two weeks and then every 1 month during the follow-up period (6 months). During each visit, complete patient assessment will be done. If any complications are detected (seroma, recurrence, wound dehiscence), it will be recorded as well.

Infection will be considered as leakage of purulent secretion through the surgical wound and not only peri-incisional hyperaemia. The suction drain will be removed when drainage became less than 20 mL per day **(11)**. Seroma will be defined as the formation of non-infected serous fluid collection beneath the flap and diagnosed by clinical examination **(12)**.

Duration of incapacity for work will be defined as the date on which patient returned to normal activities including employment and leisure activities time from the date of surgery. In addition, patients will be asked to evaluate the cosmetic appearance of the wound by looking at its picture using VAS ranging from 0-10 where 0 means the worst cosmetic outcome and 10 indicates the best cosmetic outcome. A Turkish study used a 0 to 10 visual analogue scale (VAS) scale to assess patient satisfaction with their cosmetic outcome **(13).**

2.4.5 –**Research outcome measures:**

a. Primary (main):

Postoperative recurrence rate. Recurrence will be defined as the additional outbreak of signs and symptoms of pilonidal disease after a disease-free interval following complete wound healing **(8)**.

b. Secondary (subsidiary):

1. Operative time.
2. Postoperative pain.
3. The incidence of other complications.
4. Postoperative cosmetic outcome.
5. The duration to walk, sit on toilet free from pain.
6. The duration till complete daily activities.

2.5-Data management and analysis (Details needed):

Data collection

Data will be collected by the principal investigator from Assiut University Hospital from.

Computer software

We will use SPSS version 26 for analyzing the data.

Statistical tests

Quantitative data will be presented as means ± SD. Categorical and binary variables will be tested using the χ 2 test and Fisher's exact test. Statistical significance will be assumed when $p < 0.05$.

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

(1)Esposito C, Cerulo M, Esposito G, Turco A, Borgogni R, Carulli R, et al. Endoscopic Treatment of Pilonidal Sinus Disease in Children: A Systematic Review. Journal of Laparoendoscopic & Advanced Surgical

Techniques. 2023;33(5):512-7.
(2)Konoplitskyi V, Shavliuk R, Dmytriiev D, Dmytriiev K, Kyrychenko O, Zaletskyi B, et al. Pilonidal disease: changes in understanding of etiology, pathogenesis and approach to treatment. Wiadomosci Lekarskie (Warsaw, Poland: 1960). 2019;72(8):1559-65.
(3)Harries RL, Alqallaf A, Torkington J, Harding KG. Management of sacrococcygeal pilonidal sinus disease. International Wound Journal. 2019;16(2):370-8.
(4)Grabowski J, Oyetunji TA, Goldin AB, Baird R, Gosain A, Lal DR, et al. The management of pilonidal disease: a systematic review. Journal of pediatric surgery. 2019;54(11):2210-21.
(5)Saber A, Bayumi EK. Sacrococcygeal Pilonidal Sinus Disease. In: Shiffman MA, Low M, editors. Biofilm, Pilonidal Cysts and Sinuses. Cham: Springer International Publishing; 2020. p. 215-30.
(6)Monson JRT, Weiser MR, Buie WD, Chang GJ, Rafferty JF, Buie WD, et al. Practice parameters for the management of rectal cancer (revised). Diseases of the Colon & Rectum. 2013;56(5):535-50.
(7)Manigrasso M, Velotti N, Sosa Fernandez LM, Vertaldi S, Maione F, Gennarelli N, et al. Endoscopic approach to recurrent pilonidal sinus: a retrospective analysis. Journal of Laparoendoscopic & Advanced Surgical Techniques. 2021;31(1):1-5.
(8)Milone M, Basso L, Manigrasso M, Pietroletti R, Bondurri A, La Torre M, et al. Consensus statement of the Italian society of colorectal surgery (SICCR): management and treatment of pilonidal disease. Techniques in Coloproctology. 2021:1-12.
(9)Cihan A, Ucan BH, Comert M, Cesur A, Cakmak GK, Tascilar O. Superiority of asymmetric modified Limberg flap for surgical treatment of pilonidal disease. Diseases of the colon & rectum. 2006;49:244-9.
(10)Crichton N. Visual analogue scale (VAS). J Clin Nurs. 2001;10(5):706-6.
(11)Tavassoli A, Noorshafiee S, Nazarzadeh R. Comparison of excision with primary repair versus Limberg flap. International Journal of Surgery. 2011;9(4):343-6.
(12)Arnous M, Elgendy H, Thabet W, Emile SH, Elbaz SA, Khafagy W. Excision with primary midline closure compared with Limberg flap in the treatment of sacrococcygeal pilonidal disease: a randomised clinical trial. The Annals of The Royal College of Surgeons of England. 2019;101(1):21-9.
(13)Ertan T, Koc M, Gocmen E, Aslar AK, Keskek M, Kilic M. Does technique alter quality of life after pilonidal sinus surgery? The American journal of surgery. 2005;190(3):388-92.

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

3.1. Risk – benefit assessment:

Risk of complications after surgery included infection, wound dehiscence, and recurrence.

Benefit by removing sinus tracts which will significantly improve patient satisfaction and quality of life.

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

Principle investigator should maintain a confidential list of patients included in the study along with their national IDs so that patients can be identified at a later date for follow-up and validation if required. This list should be stored in line with Assiut university data protection laws.

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

two-stage endoscopic stone extraction followed by laparoscopic cholecystectomy.

single-stage laparoscopic CBD exploration and cholecystectomy.

3.4. Informed consent.

Informed consent will be obtained from the participants before the enrollment and after explaining 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.**

موافقة للاشتراك في البحث العلمي:
اسم الباحث: أحمد ضيفي كمال محمد
عنوان البحث: تقييم نتائج السديلة المعينية في العلاج الجراحي للناسور العصعصي المتكرر مقابل الخياطة العميقة

نوع البحث : عشوائي منضبط
مكان اجراء البحث: قسم الجراحة العامة – مستشفيات جامعة أسيوط
أنت مدعو(ة) للمشاركة ببحث علمي سري سيجرى في قسم الجراحة العامة - مستشفيات جامعة اسيوط. الرجاء أن تأخذ(ي) الوقت الكافي لقراءة المعلومات التالية بتان قبل أن تقرر(ي) أذا كنت تريد(ين) المشاركة أم لا. بإمكانك طلب ايضاحات او معلومات اضافية عن اي شيء مذكور في هذه الاستمارة او عن هذه الدراسة ككل من طبيبك.
ويتعهد الباحث بانه قد تم وصف للمريض البحث العلمي وهدفه وتفسير مجرياته، الفوائد التي تنتج عن هذا البحث، التأثيرات السلبية التي يمكن أن يسببها هذا البحث، الطرق البديلة للوصول للهدف المرجو.
وأيضا في حالة الموافقة على المشاركة في هذه الدراسة سيبقى اسمك طي الكتمان. لن يكون لأي شخص, ما لم ينص القانون على ذلك, حق الاطلاع على ملفك الطبي باستثناء الطبيب المسئول عن الدراسة و معاونيه ولجان الاخلاق المهنية المستقلة و مفتشين من الادارات الحكومية المنظمة.
اذا حصل اي عارض سلبي من جراء المشاركة في هذه الدراسة لن يكون هناك اي تعويضات مالية.
أقر انا)_____أسم المريض او ممثله القانوني او وليه الجبري او وصيه اذا كان المريض قاصرا او غير قادرا على التوقيع (بان الطبيب قد شرح البحث العلمي و هدفه و فوائده والتأثيرات السلبية التي قد يسببها, وايضا المضاعفات التي قد تنتج عن الجراحة اثناء وبعد العملية. وانني اوافق على اجراء العملية والمشاركة في البحث العلمي ونشر اي معلومات او بيانات خاصة بالجراحة.

أسم الباحث: أسم المريض:
التوقيع: 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 Scopusأو 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.	Abd El-Moniem Ismail Mohamad El-Khateeb	**supervisior**	Abdelmoneam.elkhateb@med.au.edu.eg	01005022533	General surgery	
2	Lect.	Ahmed Mohamed Ali Abdullah	**supervisior**	Ahmed.abdallah6@med.au.edu.eg	01000363039	General surgery	
3	Lect.	Moamen shalkamy abdelgawad	**supervisior**	Moamen.shalkamy@aun.edu.eg	01017520093	General surgery	
4	G.P.	Ahmed Dify Kamal Mohamed	Researcher	Ahmeddify94@gmail.com	01022552241	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.