Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

Comparison of Limberg Flap and Karydakis Flap Surgery in Pilonidal Sinus Disease

Protocol summary

Study aim

The aim of this study was the comparison between two karydakis and Limberg procedures in measuring the post-operation complication, pain, and satisfaction after 6 months by pain visual analog scale (VAS).

Design

A Single blind, randomized parallel clinical trial

Settings and conduct

Pilonidal disease is common in young man. While various surgical techniques have been defined for treating Intergluteal pilonidal disease (IPD), controversy still exists as to the best surgical technique. efficiency and short-term results of the Limberg flap with that of the Karydakis flap for treating IPD are still unclear. This study compares these 2 procedures in restoring the post-operation pain, satisfaction, complication, and recurrence during 6 months by VAS. This is the randomized Single-blind clinical trial being performed from October 2016 to September 2017 on pilonidal disease patients who met inclusion criteria in Imam Khomeini hospital, Mazandaran University of Medical Sciences, Sari, Iran. The study participants were blinded using closed dressing.

Participants/Inclusion and exclusion criteria

Inclusion criteria in the study were Pilonidal disease who referred to Imam Khomeini Hospital, Sari, Iran with an age limitation of 15-65 years. Exclusion criteria were elderly patients with comorbidity diseases, scars from previous pilonidal surgery, abscess presentation, Patients with diabetes mellitus, immunodeficiency, neurological disorder, drug addiction, alcoholism, ASA 3–4, those who are under 15 and over 65.

Intervention groups

The patients were assigned to two study groups; the Limberg Flap (LF) group and the Karydakis Flap (KF) group.

Main outcome variables

Pain, Complication, Satisfaction, Cosmetics, Recurrence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141218020364N8**
Registration date: **2018-03-03, 1396/12/12**
Registration timing: **retrospective**

Last update: **2018-03-03, 1396/12/12**
Update count: **0**

Registration date

2018-03-03, 1396/12/12

Registrant information

Name

Mohhammad Yasin Karami

Name of organization / entity

Country

Iran (Islamic Republic of)

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karamiy@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

2016-10-22, 1395/08/01

Actual recruitment end date

2017-11-06, 1396/08/15

Trial completion date

empty

Scientific title

Comparison of Limberg Flap and Karydakis Flap Surgery in Pilonidal Sinus Disease

Public title
Limberg Flap and Karydakis Flap Surgery For Pilonidal Sinus Disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Intergluteal Pilonidal Disease Age more than 15 year Age less than 65 year
Exclusion criteria:
Elderly patients with co-morbidity diseases Scars from previous pilonidal surgery Abscess presentation Patients with diabetes mellitus, immunodeficiency, neurological disorder Drug addiction Alcoholism American Society of Anesthesiologists physical status classification 3–4 Those who are under 15 and over 65 Those whose pilonidal sinus orifice was located away more than 3 cm
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **80**
Actual sample size reached: **65**
Randomization (investigator's opinion)
Randomized
Randomization description
The random drawing of sealed envelopes (Computer-based table of randomization)
Blinding (investigator's opinion)
Single blinded
Blinding description
The study participants had known two types of common pilonidal off-midline flap surgery treatment, But due to the dressing on the wound, they were not aware of the type of treatment we were used for them. The observer who completed the questionnaire did know the study groups. The original researcher (surgeon) was aware of the study groups. The data analyzer was not known from the study groups. The safety committee and data monitoring were aware of the study groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
Valie Asr highway
City
Sari
Province
Mazandaran
Postal code
984815733971
Approval date
2016-10-19, 1395/07/28
Ethics committee reference number
IR.MAZUMS.REC.95.2392

Health conditions studied

1

Description of health condition studied
Pilonidal Sinus Disease
ICD-10 code
L05.9
ICD-10 code description
Pilonidal cyst and sinus without abscess

Primary outcomes

1

Description
Pain
Timepoint
Patients were visited weekly for the first month and subsequently every 3 months for the first 6 months
Method of measurement
Visual Analogue Score

2

Description
Duration of Surgery
Timepoint
During operation
Method of measurement
Evaluated by Surgeon

3

Description
Satisfaction
Timepoint
Patients were visited weekly for the first month and subsequently every 3 months for the first 6 months
Method of measurement
Visual Analogue Score

4

Description
Complication
Timepoint
Patients were visited weekly for the first month and subsequently every 3 months for the first 6 months
Method of measurement
Direct supervision by the surgeon

Secondary outcomes

1

Description
Recurrence Rate
Timepoint
Patients were visited weekly for the first month and subsequently every 3 months for the first 6 months
Method of measurement
Follow up by surgeon

Intervention groups

1

Description
First Intervention group: The Limberg flap (LF) group, Rhomboid excision was performed, the lower end being 2 cm lateral to the midline and covering the whole area where the sinus spread. Using electrocautery, hemostasis was provided. In order to ensure tension-free repair, the flap was released at the bottom including gluteal fascia and then slid to medial in order to cover the defect. A suction drain was applied to the region in all patients. The subcutaneous tissue was closed with 2-fold 2/0 polyglactin suture (Ethicon US, LLC, Cincinnati, Ohio), and the skin was closed with 3/0 polypropylene (Ethicon US, LLC) mattress suture. When the drain amount fell below 40 mL/d, it was removed.
Category
Treatment - Surgery

2

Description
Second Intervention group: The Karydakis Flap (LF) group, In this group an asymmetrical elliptic excision was done, lower and upper ends being located at approximately 2 cm lateral to the natal cleft, and all defective tissues were removed until reaching to the healthy borders. After that, the medical wound edge was mobilized, and the flap was slid by suturing to the fascia and skin suitable wound layers on the lateral wound edge corresponding to one another. The subcutaneous tissue was closed with 2-fold 2/0 polyglactin suture, and the skin was closed with 3/0 polypropylene mattress suture. In all patients, a suction drain was applied to the region. When the drain amount fell below 40 mL/d, it was removed.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Mina Alvandipoor
Street address
Razi Ave
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984816633131
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
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Dr Majid Saeedi
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Mazandaran
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9848175861
Phone
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Email
majsaeedi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sari University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mohhammad Yasin Karami

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
General Surgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable