

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

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

Protocol summary

Study aim

The aim of this study was the comparison between two karydakias 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 Karydakias 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 Karydakias 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

Mohammad Yasin Karami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3839 1385

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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

Public title

Limberg Flap and Karydakias 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 Karydakias 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

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Razi Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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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
Mohammad Yasin Karami
Position
Assistant Professor
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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