Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of two methods of abscess drainage with delayed surgery and early cyst removal in patients with pilonidal cyst referred to Rafsanjan Ali Ibn Abi Talib hospital Rafsanjan city: 2023

Protocol summary

Study aim

1- Comparison of the frequency of wound infection, hematoma formation, seroma formation, wound cellulitis, after pilonidal surgery in two groups 2- Comparison of the total hospital cost of the two groups 3- Comparison of the duration of hospitalization of patients in two groups

Design

A parallel-group, single-blind, randomized, phase 2 clinical trial of 100 patients. The rand function of Excel software was used for randomization.

Settings and conduct

This study will be conducted in Ali Ibn Abi Talib Hospital in Rafsanjan in 2023. Patients who are candidates for pilonidal cyst surgery will enter the study after informed consent and will be randomly assigned to one of the intervention groups. After surgery, the checklist of study variables including some surgical complications, duration of surgery and hospitalization cost will be completed by project partners. Finally, the data analyst, who does not know about the grouping, will analyze the data.

Participants/Inclusion and exclusion criteria

Conditions for entering the study: informed consent to participate in the study, ages between 15 and 50 years Conditions for not entering the study: history of skin disease including psoriasis, ichthyosis, pemphigus, history of diseases that weaken the immune system, history of taking corticosteroids, history of previous pilonidal cyst surgery

Intervention groups

Group 1: They will undergo incision and drainage of the abscess and will be discharged with the prescription of antibiotics, and the surgery to remove the pilonidal cyst will be performed in a delayed manner (one month later). Group 2: They will undergo drainage and surgical removal of the pilonidal cyst during a single operation.

Main outcome variables

wound site infection; hematoma formation; seroma formation; Cellulitis of the wound area

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230703058656N1**
Registration date: **2023-07-25, 1402/05/03**
Registration timing: **prospective**

Last update: **2023-07-25, 1402/05/03**
Update count: **0**

Registration date

2023-07-25, 1402/05/03

Registrant information

Name

Bahar Noori-Rahmatabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 6194

Email address

baharnoori64@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-03-18, 1402/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of two methods of abscess drainage with delayed surgery and early cyst removal in patients with pilonidal cyst referred to Rafsanjan Ali Ibn Abi Talib hospital Rafsanjan city: 2023

Public title
Comparison of two methods of abscess drainage with delayed surgery and early cyst removal in patients with pilonidal cyst

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent to participate in the study Age 15-50 years
Exclusion criteria:
History of skin disease including psoriasis, ichthyosis, pemphigus History of diseases that weaken the immune system History of corticosteroids History of pilonidal cyst surgery

Age
From **15 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
The data analyzer will not know about the grouping

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Rafsanjan University of Medical Sciences
Street address
Vice President of Research and Technology, Rafsanjan University of Medical Sciences, Imam Ali Blvd., Rafsanjan
City
Rafsanjan
Province
Kerman
Postal code
7717933777

Approval date
2021-11-15, 1400/08/24

Ethics committee reference number
IR.RUMS.REC.1400.186

Health conditions studied

1

Description of health condition studied
Pilonidal cyst and sinus with abscess

ICD-10 code
L05.0

ICD-10 code description
Pilonidal cyst and sinus with abscess

Primary outcomes

1

Description
cellulite

Timepoint
3, 6 and 30 days after surgery

Method of measurement
Examination and observation

2

Description
Wound infection

Timepoint
3, 6 and 30 days after surgery

Method of measurement
Examination and observation

3

Description
Wound hematoma

Timepoint
3, 6 and 30 days after surgery

Method of measurement
Examination and observation

4

Description
Surgical wound seroma

Timepoint
3, 6 and 30 days after surgery

Method of measurement
Examination and observation

5

Description
Opening of the surgical wound
Timepoint
3, 6 and 30 days after surgery
Method of measurement
Examination and observation

6

Description
Duration of surgery
Timepoint
From the start of surgery until the patient enters recovery
Method of measurement
Timer

7

Description
Cost of hospitalization
Timepoint
Discharge time from the hospital
Method of measurement
Rial

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Cyst evacuation by delayed surgery
Category
Treatment - Surgery

2

Description
Intervention group: primary cyst removal
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali ebn Abitalib Hospital
Full name of responsible person
Seyyed Mohammad Ebrahim Pourhosseini
Street address
Ali Ibn Abi Talib Square, Imam Ali Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Reza vazirinejad
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Central organization of the University of Medical Sciences, Imam Ali Blvd
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rafsanjan 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
Rafsanjan University of Medical Sciences
Full name of responsible person
Masoumeh Taghizadeh
Position
Assistant Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals.
When the data will become available and for how long
6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Sending data can only be done by presenting an official letter from the institution.
From where data/document is obtainable
To receive information, refer to the Research Vice-Chancellor of Rafsanjan University of Medical Sciences.
What processes are involved for a request to access data/document
After the approval of the Research Vice-Chancellor of Rafsanjan University of Medical Sciences, the data will be provided to the applicant.
Comments