

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

City

Rafsanjan

Province

Kerman

Postal code

7717937555

Phone

+98 21 3428 0000

Email

aliebn_hospital@rums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Reza vazirinejad

Street address

Central organization of the University of Medical Sciences, Imam Ali Blvd

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 0038

Email

vcrt@rums.ac.ir

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

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Ali Ibn Abi Talib Square, Imam Ali Blvd

City

Rafsanjan

Province

Kerman

Postal code

7717937555

Phone

+98 34 3428 0000

Email

Staghi16@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Masoumeh Taghizadeh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Ali Ibn Abi Talib Square, Imam Ali Blvd

City

Rafsanjan

Province

Kerman

Postal code

7717937555

Phone

+98 34 3428 0000

Email

Staghi16@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Bahar Noori-Rahmatabadi

Position

Assistance professor of Anesthesiology&Intensive care

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

No.68,East Emam Sajad Alley-1, Emam Sajad Blvd,
Rafsanjan Town

City

Rafsanjan

Province

Kerman

Postal code

7717943816

Phone

009834286194

Email

baharnoori64@yahoo.com

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