

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

comparison of Tension-free primary closure, secondary intention, and Limberg flap, in treatment of uncomplicated pilonidal sinus disease

Protocol summary

Summary

Abstract Aim: This study will perform to compare the efficacy and long-term outcomes of three surgical treatments for uncomplicated pilonidal sinus disease, tension-free primary closure, Limberg flap, and secondary intention (wide excision and packing).
Inclusion and exclusion criteria: Uncomplicated pilonidal sinus
Methods: randomized clinical trial study, 66 patients with uncomplicated pilonidal sinus disease will randomly assigned to be surgically treated using tension-free primary closure, Limberg flap, or secondary intention methods. The outcomes including pain, healing time, recurrence, complications, disability, reoperation, and patient satisfaction will compare between three groups after two years of follow-up.

General information

Acronym

treatment of uncomplicated pilonidal sinus

IRCT registration information

IRCT registration number: **IRCT2015121225483N1**

Registration date: **2016-02-20, 1394/12/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-20, 1394/12/01

Registrant information

Name

Babak Sabet Divshali

Name of organization / entity

Shahid beheshti university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2236 0635

Email address

sabetdivshali@gmail.com

Recruitment status

Recruitment complete

Funding source

thesis budget

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of Tension-free primary closure, secondary intention, and Limberg flap, in treatment of uncomplicated pilonidal sinus disease

Public title

treatment of pilonidal sinus disease

Purpose

Treatment

Inclusion/Exclusion criteria

uncomplicated pilonidal sinus

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahid Beheshti University of Medical Sciences

Street address

Velenjak - Kodakyar St.-Tehran

City

Tehran

Postal code**Approval date**

2012-05-13, 1391/02/24

Ethics committee reference number

117

Health conditions studied**1****Description of health condition studied**

pilonidal sinus

ICD-10 code

L05.9

ICD-10 code description

Pilonidal cyst without abscess

Primary outcomes**1****Description**

recurrence and need to reoperation

Timepoint

2-year

Method of measurement

observation

Secondary outcomes**1****Description**

pain,healing time,disability,satisfaction

Timepoint

1-month

Method of measurement

pain score

Intervention groups**1****Description**

excision of pilonidal sinus and free of tension primary closure excision of pilonidal sinus and and secondary intention (daily dressing till complete healing) excision of pilonidal sinus and rapare of sinus with liimberg flap

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Moddares teaching hospital

Full name of responsible person

Babak sabet M.D.-MSc

Street address

surgical ward-moddares teaching hospital-Sadat Abad-Tehran

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr.babak sabet

Street address

Surgical ward,Moddares teaching hospital - Saadat abad-Tehran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin
Type of organization providing the funding
empty

+98 21 2236 0635

Fax
Email
sabet@crc.mui.ac.ir
Web page address

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr.Babak Sabet Divshali
Position
Assistant professor of surgery
Other areas of specialty/work
Street address
Surgical ward,Moddares teaching hospital - Sadat
abad-Tehran
City
Tehran
Postal code
Phone
+98 21 2236 0635
Fax
Email
sabet@crc.mui.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr babak Sabet Divshali
Position
Assistant professor of surgery
Other areas of specialty/work
Street address
Moddares teaching hospital, Sadat Abad-Tehran
City
Tehran
Postal code
Phone

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Babak sabet divshali
Position
Assistant professor
Other areas of specialty/work
Street address
Surgical ward-Moddares teaching hospital-Sadat
Abad-Tehran hospital
City
Tehran
Postal code
Phone
+98 21 2236 0635
Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty