Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 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
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Shahid beheshti university of medical sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source
thesis budjet

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
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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

Person responsible for general inquiries

Contact
Name of organization / entity
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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