Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Cure and Relapse Rate of the Symptoms in Umbilical Pilonidal Sinus in two surgical way complete sinus excision with reconstruction of umbilicus and sinus excision with umbilical preservation

Protocol summary

Summary

60 patients with umbilical pilonidal sinus who had not undergone any previous surgeries are operated on using two techniques that group1(30 patients) involves complete excision of the sinus after eversion of the umbilicus are followe by reconstruction of the umbilicus. in group2(30 patients) Under general anesthesia, reveale a 3-mm ulcerated site in the depth of the umbilicus from which bits of hair protruded. A vertical skin incision through the umbilicus skirting one side of the sinuses was made. Diathermy cutting use to minimize bleeding and ensure visibility of the lesion.the tract were completely excised. The skin close primarily and patients in two groups give 3 course of antibiotics. Patients then followe and wound complications, recurrence, and patient satisfaction evaluate at 1 week,2 week,1 month,3 month,6 month postoperative visits.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013011912172N1**
Registration date: **2013-03-08, 1391/12/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-03-08, 1391/12/18

Registrant information

Name
Mahdieh Amirbeigy
Name of organization / entity
Kashan University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 36 1555 0021
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amirbeigy@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Cure and Relapse Rate of the Symptoms in Umbilical Pilonidal Sinus in two surgical way complete sinus excision with reconstruction of umbilicus and sinus excision with umbilical preservation

Public title

Comparison of Cure and Relapse Rate of the Symptoms in Umbilical Pilonidal Sinus in two surgical way complete sinus excision with reconstruction of umbilicus and sinus excision with umbilical preservation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:purulent or bloody discharge and itching from the umbilicus;bits of hair or granulation tissue in the depths of the umbilicus. Exclusion criteria:fever;intra-abdominal symptoms; epidermal

cysts;endometriosis;omphalomesenteric duct remnants;urachal anomalies;benign or malignant tumor;history of laparotomy; previous abdominal surgery.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kashan University of Medical Sciences and Health Services

Street address
Medical college, Ghotb Ravandi boulevard

City
Kashan

Postal code

Approval date
2012-10-27, 1391/08/06

Ethics committee reference number
2880/1/5/29/پ

Health conditions studied

1

Description of health condition studied
Pilonidal cyst

ICD-10 code
L05.9

ICD-10 code description
Pilonidal cyst without abscess

Primary outcomes

1

Description
Cure of umbilical pilonidal sinus

Timepoint
one week two weeks one month three months six months

Method of measurement
observation , questionnaire

Secondary outcomes

1

Description
relapse of umbilical pilonidal sinus

Timepoint
one week two weeks one month three months six months

Method of measurement
obsevation, questionnaire

Intervention groups

1

Description
complete sinus excision with reconstruction of umbilicus

Category
Treatment - Surgery

2

Description
pilonidal sinus excision with umbilical preservation

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital

Full name of responsible person
Dr Mahdieh Amirbeigy

Street address
Shahid Beheshti Hospital, Ghotb ravandi boulevard, kashan

City
Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kashan University of Medical Sciences and Health Services

Full name of responsible person

Dr Qolam Ali Hamidi

Street address

Medical college, Ghotb Ravandi boulevard

City

Kashan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Kashan University of Medical Sciences and Health Services

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

Kashan University of Medical Siences and Health Services

Full name of responsible person

Dr Mahdieh Amirbeigy

Position

General surgen resident

Other areas of specialty/work

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Assistant professor

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Contact

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Other areas of specialty/work

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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