

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 followed by reconstruction of the umbilicus. in group2(30 patients) Under general anesthesia, revealed 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 used to minimize bleeding and ensure visibility of the lesion. The tract were completely excised. The skin closed primarily and patients in two groups give 3 courses of antibiotics. Patients then followed and wound complications, recurrence, and patient satisfaction evaluated at 1 week, 2 weeks, 1 month, 3 months, 6 months 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)

Phone

+98 36 1555 0021

Email address

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 Sciences 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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Person responsible for updating data

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Other areas of specialty/work

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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