

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Assignment and comparison of the effectiveness of two methods“ Vertical mattress suture and Tie-over” surgical treatment for pilonidal patients

Protocol summary

Summary

A comparative study on the efficacy results of two surgical methods (VMS) Vertical mattress suture and (TO) Tie-over was performed on all patients admitted to hospital for elective surgery in Kashani hospital, Shahrekord, Iran with a sample size whit power 90% and 95% CI , each group, 35 persons and a total of 70 patients were determined. Simple uncomplicated divided randomly into two equal groups, total lesion was fixed vertical to the sacral fascia. Then a wound healing assay whit VMS method and the other group with TO. For each group, questionnaire design were recorded data including age, sex, occupation, history of familial diseases, smoking, BMI, Hb, duration of disease, acute or chronic (chronic disease for more than 3 weeks), symptoms at presentation (pain, discharge sense of mass), anesthesia (general, spinal), type of wound healing (VMS or tO), there's hair or lack of it, the duration of surgery, use of drains, wound complications, short-term study, during the patient's stay in hospital, the wound healing time and duration of its inability to work. Then he or she recorded VAS for pain a month later and VAS for cosmetic 3 months after .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301073156N2**
Registration date: **2013-01-18, 1391/10/29**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-01-18, 1391/10/29

Registrant information

Name

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Name of organization / entity

Shahrekord University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Department of Research and Technology , shahrekord university of medical sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2012-12-20, 1391/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assignment and comparison of the effectiveness of two methods“ Vertical mattress suture and Tie-over” surgical treatment for pilonidal patients

Public title

Assignment and comparison of the effectiveness of two methods“ Vertical mattress suture and Tie-over” surgical treatment for pilonidal patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients with pilonidal sinus (Sakrvkvsyzhyal) referred to Kashani hospital
Exclusion criteria: patients with pilonidal sinus (Sakrvkvsyzhyal) who have relapsed or abscess

Age

No age limit

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: 70

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

shahrekord university of medical sciences

Street address

kashani st.

City

shahrekord

Postal code

Approval date

2012-05-22, 1391/03/02

Ethics committee reference number

5-3-91

Health conditions studied

1

Description of health condition studied

Pilonidal

ICD-10 code

L05

ICD-10 code description

Pilonidal cyst

Primary outcomes

1

Description

pain

Timepoint

three months for follow up

Method of measurement

observation , questionnaire

Secondary outcomes

1

Description

cosmetic

Timepoint

three months

Method of measurement

obsevation, questionnaire

Intervention groups

1

Description

a group fix with a VMS method . Techniques VMS: After removing , the skin and under the skin flap on the side of the lesion with less tissue removed. It is repaired with karydakys principles in the area lateral to the midline Then it is repaired using zero nylon fabric and is made to get total tissue and pre-sacral fascia. The sutures distention is about one centimeter.

Category

Treatment - Surgery

2

Description

the other group fix with TO method . Techniques TO: After removing , the skin and under the skin flap on the side of the lesion with less tissue removed. It is repaired with karydakys principles in the area lateral to the midline . Then the cutaneous and subcutaneous is restored separately using the two zero nylon suture. The wound is made with three sutures that include together cutaneous , subcutaneous and pre-sacral fascia with zero nylon And inserting the following two gas tube and stitches it took to close

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

kashani hospital

Full name of responsible person

Street address**City**

shahrekord

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

Department of Research and Technology

Full name of responsible person

dr. mohmmod mobasheri

Street address

kahsani st.

City

shahrekord

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

Yes

Title of funding source

Department of Research and Technology

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**

shahrekord university of medical sciences

Full name of responsible person

dr. mohammad moazeni bistgani

Position

thoracic surgeon

Other areas of specialty/work**Street address**

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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*