Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assignment and comparation 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, quastionnaire 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

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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 comparation of the effectiveness of two methods‟ Vertical mattress suture and Tie-over” surgical treatment for pilonidal patients

Public title

Assignment and comparation 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 sciemces
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
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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