

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Routine Method dressing , Hydrocolloid and Aliginats dressing with standard method and modified method in healing process of pilonidal sinus surgery

Protocol summary

Summary

Today, various products containing various compounds are used in wound dressings. Here, we are aiming to compare the efficiency of alginate and hydrocolloidal wound dressing products with the efficiency of products used in the conventional, routine methods. To do so, 60 patients will be randomly divided in three groups of 20 (aged 18 to 40 who do not have diabetes, and do not suffer from paralysis or related problems) and will be randomly treated by a different dressing methods. The three dressing methods include routine method (using normal saline and wet sponge), standardized method recommended for alginate and hydrocolloidal compounds and the modified version of the previous method in which some changes have been made in the direction of use of the products. In the next step, for each patient in each group, the total number of dressing changes and duration of wound healing (in days) as well as the level of pain experienced by the patients during each dressing change will be recorded and compared. The level of pain during dressing change will be assessed by a Johnson's pain assessment ruler in the scale of 1-10. Furthermore, the depth, width and length of the wound will be measured weekly and will be compared with its initial dimensions right after the surgery. Meanwhile, the patients who do not go on the dates specified for dressing change and the patients with surgical complications will be excluded from the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014072118553N1**

Registration date: **2014-08-28, 1393/06/06**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-08-28, 1393/06/06

Registrant information

Name

Leila Sadati

Name of organization / entity

Alborz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 26 3253 4221

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Recruitment status

Recruitment complete

Funding source

Alborz University Of Medical Sciences

Expected recruitment start date

2014-09-01, 1393/06/10

Expected recruitment end date

2015-01-30, 1393/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Routine Method dressing , Hydrocolloid and Aliginats dressing with standard method and modified method in healing process of pilonidal sinus surgery

Public title

comparison of 3 methods in pilonidal wound dressing

Purpose
Treatment

Inclusion/Exclusion criteria
inclusion criteria: between 18-40 year; surgery by one method and surgeons with similar experience; not obese with BMI<18.5;good diet; free of symptoms and a history of diabetes; no signs of paralysis or immobility; exclusion criteria: Patients who do not refer for dressing on determined date ; Patients who have complications after surgery such as bleeding and the need to have more attention.; Patients who volunteer and the treatment are subject to a special diet.

Age
From **18 years** old to **40 years** old

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)
Triple blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Alborz University of medical Sciences Ethics Committee

Street address
Research unit,Dara Department, Golshahr ST, karaj, Iran

City
Karj

Postal code

Approval date
2014-05-26, 1393/03/05

Ethics committee reference number
2375591

Health conditions studied

1

Description of health condition studied

PILONIDAL SINUS

ICD-10 code

Y70-Y82

ICD-10 code description

XII Diseases of the skin and subcutaneous tissue

Primary outcomes

1

Description

wound healing

Timepoint

weekly

Method of measurement

centimeter-junson ruller

Secondary outcomes

1

Description

pain

Timepoint

weekly

Method of measurement

jonsen ruller

Intervention groups

1

Description

control group: dressing by normal saline and sponge as a routine method,

Category

Other

2

Description

first intervention group:dressing by hydroclloid and alginate compounds by standard method that recommended by company.

Category

Other

3

Description

second intervention group: dressing by alginate and hydrocolloidal compounds in the modified version that researcher will introduced it.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital (Karaj)

Full name of responsible person

Dr Ahmad Elahi

Street address

Shahid Bahonar Hospital (karaj)

City

karaj

2

Recruitment center

Name of recruitment center

professional clinic of alborz

Full name of responsible person

Dr ahmad Elahi

Street address

professional clinic of alborz, Shahid Beheshti ST,
Karaj, Iran

City

karaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Deputy of Research-Dr Gharavi

Street address

Deputy of Research, Dara department, Golshahr ST,

City

karaj

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

Yes

Title of funding source

Alborz 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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Full name of responsible person

Leila-sadati

Position

Faculty member

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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