

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 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 Universty of Medical Scincences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 26 3253 4221

###### Email address

sadati@abzums.ac.ir

##### 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

jonson 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**

Alborz University of Medical Sciences

**Full name of responsible person**

Leila-sadati

**Position**

Faculty member

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

Paramedicine faculty, Golestan 6 Ave, Baghestan St.

**City**

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**Postal code**

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**Phone**

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**Fax****Email**

l.sadati70@gmail.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Email**

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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*