

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Comparison of open pilonidal sinus surgical wound healing following dressing by honey, olive oil, normal saline and honey-olive oil mixture

#### Protocol summary

##### Summary

Study purpose : comparison of the healing of pilonidal sinus wound(Created after open surgery) after dressing with honey, olive oil, normal saline, combination of olive oil and honey. The size of the skin defect after pilonidal sinus open surgery between 5 and 10 cm, is an inclusion criteria. Autoimmune and chronic diseases, infectious abscess, long-term use of corticosteroids and history of chemotherapy are the exclusion criteria. Study population is all patients under pilonidal sinus open surgery referred to Khorramabad Shohada Ashayer Hospital. The sample size is 168 patients; that will be allocated to the intervention group (according to the title of study) and a control group (receiving normal saline alone). Double-blind study for researcher and analyser will be conducted. After the surgery in the operating room, in each of the four groups on the surgical site wound, washing with wet sterile gas and normal saline, will be performed. Then daily washing with normal saline will be done for a week. And then daily desired dressing (honey, olive oil, or both) in a uniform layer on the wound will be performed. In the control group, the same process as a month, daily washing with normal saline alone will continue. All groups after four weeks, see a doctor and wound healing, new tissue formation at the surgical site and local infection will be observed and recorded. Next visit and check for recurrence, three months later will be done.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015012020734N1**

Registration date: **2015-07-06, 1394/04/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-07-06, 1394/04/15

##### Registrant information

###### Name

Younes Azizpourfard

###### Name of organization / entity

Lorestan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 919 038 3060

###### Email address

dr.azizpourfard@lums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for research of Lorestan University of Medical Sciences.

##### Expected recruitment start date

2015-03-21, 1394/01/01

##### Expected recruitment end date

2015-06-20, 1394/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of open pilonidal sinus surgical wound healing following dressing by honey, olive oil, normal saline and honey-olive oil mixture

##### Public title

Comparison of open pilonidal sinus surgical wound healing following dressing by honey, olive oil, normal saline and honey-olive oil mixture

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: 15-40 years old; the size of the skin defect after pilonidal sinus open surgery between 5 and 10 cm. Exclusion criteria: Diabetes, heart disease, renal, infectious abscess, an autoimmune disease, a history of chemotherapy, long-term use of corticosteroids.

## Age

From **15 years** old to **40 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **168**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

samples will randomly placed in each of the four groups.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

##### Street address

3th km to khgoramabad-Boroujerd road

##### City

khgoramabad

##### Postal code

##### Approval date

2015-06-14, 1394/03/24

##### Ethics committee reference number

LUMS.REC.1394.12

## Health conditions studied

### 1

#### Description of health condition studied

Pilonidal cyst

#### ICD-10 code

L05

## ICD-10 code description

fistula sinus coccygeal or pilonidal

## Primary outcomes

### 1

#### Description

Healing of pilonidal sinus wound (after open surgery)

#### Timepoint

One month and three months after intervention

#### Method of measurement

Assessed by the surgeon

### 2

#### Description

Infection of pilonidal sinus wound (after open surgery)

#### Timepoint

One month and three months after intervention

#### Method of measurement

Assessed by the surgeon

## Secondary outcomes

### 1

#### Description

Adverse reactions (allergy)

#### Timepoint

In all phases of the project

#### Method of measurement

By examination and regular visits and patient complaints

### 2

#### Description

Recurrence of pilonidal sinus

#### Timepoint

In all phases of the project

#### Method of measurement

By examination and regular visits and patient complaints

## Intervention groups

### 1

#### Description

The first intervention group: dressing with honey.

#### Category

Treatment - Drugs

### 2

#### Description

The second intervention group: dressing with olive oil.

#### Category

Treatment - Drugs

### 3

#### Description

The third intervention group: dressing with a combination of honey and olive oil.

**Category**

Treatment - Drugs

**4**

**Description**

Control: washing with normal saline.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shohada Ashayer Hospital of Khorramabad

**Full name of responsible person**

Hormoz Mahmoudvand

**Street address**

**City**

Khorramabad

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for research of Lorestan University of Medical Sciences

**Full name of responsible person**

Dr. varzi

**Street address**

3th km to Khorramabad-Boroujerd road

**City**

Khorramabad

**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 of Lorestan 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**

Lorestan University of Medical Science

**Full name of responsible person**

Younes AzizpourFard

**Position**

Medical student

**Other areas of specialty/work**

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Assistant proffessor

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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*