

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparative trial of Aloe vera/olive oil combination cream versus placebo in repair of Surgical wounds of pilonidal disease in open surgical technique.

Protocol summary

Study aim

Determining the effect of a combination of aloevera/olive oil cream in healing of open wound of pilonidal cyst surgery

Design

Clinical trial with control group double-blind, systemic randomized sampling with 60 people in four phases.

Settings and conduct

Patients with pilonidal sinus surgery in Baqiyatallah hospital were randomly assigned (double-blinded) into intervention and placebo groups during pylonidal ulcer healing.

Participants/Inclusion and exclusion criteria

Inclusion criteria: pilonidal sinus, open surgery Exclusion criteria: Diabetes mellitus; immune deficiency; pregnancy; Lactation

Intervention groups

The effect of a combination of olive oil and aloe vera cream on wound healing pilonidal sinus surgery and compared with the placebo group.

Main outcome variables

Improve the time of surgical wound healing of pilonidal sinus; Postoperative pain and patient satisfaction after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161209031306N2**

Registration date: **2018-07-24, 1397/05/02**

Registration timing: **retrospective**

Last update: **2018-07-24, 1397/05/02**

Update count: **0**

Registration date

2018-07-24, 1397/05/02

Registrant information

Name

ali hajihashemi

Name of organization / entity

agiattallah U.

Country

Iran (Islamic Republic of)

Phone

+98 21 8126 3591

Email address

stu.hajihashemi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative trial of Aloe vera/olive oil combination cream versus placebo in repair of Surgical wounds of pilonidal disease in open surgical technique.

Public title

Comparative trial of Aloe vera/olive oil combination cream versus placebo in repair of surgical wounds of pilonidal disease in open surgical technique.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 18 years of age
Patients under 60 years old with Pilonidal sinus
Candidate for Open Sinus Pilonidal Surgery
Referring to Baqiyatallah Hospital

Exclusion criteria:

Diabetes mellitus
immune deficiency
pregnancy
Lactation

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A systematic approach (alternative: active and placebo)

Blinding (investigator's opinion)

Double blinded

Blinding description

The medication and placebo (A and B) are available to the therapist and the patient, where medications or placebo are differentiated.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of the University of Medical Sciences of baghiatalah

Street address

Molasadra

City

Tehran

Province

Tehran

Postal code

1698741195

Approval date

2017-05-23, 1396/03/02

Ethics committee reference number

IR.BMSU.REC.1396.32

Health conditions studied

1

Description of health condition studied

Pilonidal disease

ICD-10 code

L05

ICD-10 code description

Pilonidal cyst and sinus

Primary outcomes

1

Description

Wound healing time after pilonidal sinus surgery

Timepoint

The beginning of the study and days 7; 30; 60; 90

Method of measurement

Clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Patients after the sinus surgery are divided in 1 groups of 30, who take the medication twice daily for 3 weeks.

Category

Treatment - Drugs

2

Description

Patients after the sinus surgery are divided in 1 groups of 30, who take the placebo twice daily for 3 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah hospital

Full name of responsible person

Ghafoorimanesh saeed

Street address

Mullasadra Street, Baqiyatallah Hospital

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1465793811

Phone

+98 21 8126 3591

Email

ghafour_manesh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Jalali Mohamad

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Bagheiat-allah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Ghafoorimanesh Saeed

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

A part of the information, such as information on the main outcome, can be shared.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

Email:ghafour_manesh@yahoo.com

What processes are involved for a request to access data/document

After the request is sent

Comments