

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effectiveness of ozone olive oil in wound healing of patients with pilonidal sinus treated with extensive tissue resection surgery

Protocol summary

Study aim

Determination of the effectiveness of ozone olive oil in wound healing in patients with pilonidal abscess treated with extensive tissue resection surgery

Design

A Two arm, triple blind, randomized controlled trial on 46 patients

Settings and conduct

The patients, the surgeon, the nurse who records the data and data analyser are blinded to the allocated groups

Participants/Inclusion and exclusion criteria

Age over 15 years and with the diagnosis of abscess and Pilonidal sinus undergoing surgical treatment with extensive tissue resection

Intervention groups

In patients with operated pilonidal sinus abscess, conventional dressing and dressing with ozone olive oil are performed and the wound healing process is compared between the two groups

Main outcome variables

The severity of pain, infection, bleeding and wound healing

General information

Reason for update

The project manager's mistake in registering the sample size

Acronym

IRCT registration information

IRCT registration number: **IRCT20190423043356N3**

Registration date: **2022-01-26, 1400/11/06**

Registration timing: **prospective**

Last update: **2023-12-25, 1402/10/04**

Update count: **1**

Registration date

2022-01-26, 1400/11/06

Registrant information

Name

Amin Dalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3180 2557

Email address

daliliam@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of ozone olive oil in wound healing of patients with pilonidal sinus treated with extensive tissue resection surgery

Public title

Evaluation of the effectiveness of ozone olive oil in wound healing of patients with pilonidal sinus treated with extensive tissue resection surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of the pilonidal sinus by the surgeon
Extensive removal of tissue Age between 15-65

Exclusion criteria:

Age less than 15 years Patient dissatisfaction Past surgical history

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be individually randomized using block randomization method in quadruple blocks by randomization.com website, Allocation concealment will be done using sealed, opaque, and sequentially numbered envelopes

Blinding (investigator's opinion)

Triple blinded

Blinding description

Researcher, Patients, The nurse who collects the data, Data analyzer

Placebo

Used

Assignment

Parallel

Other design features

It is a diagnostic and therapeutic method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ibn-e-Sina St, Imam Reza Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

009851

Approval date

2021-10-30, 1400/08/08

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.484

Health conditions studied

1

Description of health condition studied

Pilonidal sinus

ICD-10 code

K60

ICD-10 code description

Pilonidal sinus

Primary outcomes

1

Description

The severity of pain

Timepoint

Daily visits and then every other day up to 10 days and then weekly until the wound heals

Method of measurement

Physical examination by the surgeon and VAS score

2

Description

The severity of the bleeding

Timepoint

Daily visits and then every other day up to 10 days and then weekly until the wound heals

Method of measurement

Physical examination by the surgeon

3

Description

Infection

Timepoint

Daily visits and then every other day up to 10 days and then weekly until the wound heals

Method of measurement

Physical examination by the surgeon

4

Description

Wound healing

Timepoint

Daily visits and then every other day up to 10 days and then weekly until the wound heals

Method of measurement

Physical examination by the surgeon

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: standard treatment and ozone olive oil ointment

Category

Treatment - Drugs

2

Description

Control group: Standard treatment (daily irrigation with Normal Saline serum and dressing)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Amin Dalili

Street address

Ibn-e-Sina St., Imam Reza Hospital

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Phone

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Daliliam@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Ghoreshi building, Daneshgah St.

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Amin Dalili

Position

Asistant professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available