Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 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)
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+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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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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Person responsible for updating data

Contact

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Position
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Latest degree
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General Surgery

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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