

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The Effectiveness of Ozone Olive Oil on healing of Acute Perianal Fissure

Protocol summary

Study aim

The Effectiveness of Ozone Olive Oil on healing of Acute Perianal Fissure

Design

A two-arm, triple-blind, randomized controlled trial on 60 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

In this study, all patients with acute fissure with age range of 18-65 years and without gender restrictions, who are candidates for medical treatment, will enter the study. Exclusion criteria include the previous history of anal surgery, comorbidities (diabetes), IBD disease, STD disease around the anus, TB disease, anorectal cancers, immunodeficiency

Intervention groups

The first group undergo standard treatment for patients with acute perianal fissure, sitting in warm water, use of laxative and stool bulking twice a day with plain olive oil ointment as a placebo (prepared and formulated by Nasim Ozon Urmia Company). One cc is given twice a day. The second group, in addition to the standard treatment of patients with acute perianal fissure, treat with the topical formulation of ozone olive oil ointment (by Nasim Ozon Company).

Main outcome variables

The severity of pain, bleeding, itching and wound healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190423043356N1**

Registration date: **2020-07-18, 1399/04/28**

Registration timing: **prospective**

Last update: **2020-07-18, 1399/04/28**

Update count: **0**

Registration date

2020-07-18, 1399/04/28

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

2020-09-22, 1399/07/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Ozone Olive Oil on healing of Acute Perianal Fissure

Public title

The Ozone Olive Oil on healing of Acute Perianal Fissure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with acute perianal fissure Age between 18-65 Undergoing medical treatment

Exclusion criteria:

Previous perianal surgery
Commodities like Diabetes, IBD, STD, TB
Anorectal cancers
Immunodeficiency diseases

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

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 analyser

Placebo

Used

Assignment

Parallel

Other design features**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

2020-01-21, 1398/11/01

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.820

Health conditions studied**1****Description of health condition studied**

Acute perianal fissure

ICD-10 code

K60.0

ICD-10 code description

Acute anal fissure

Primary outcomes**1****Description**

The severity of pain

Timepoint

Weekly follow up till 2 months

Method of measurement

Physical examination by surgeon and VAS score

2**Description**

Bleeding

Timepoint

Weekly follow up till 2 months

Method of measurement

Physical examination by surgeon

3**Description**

Itching

Timepoint

Weekly follow up till 2 months

Method of measurement

Patient report in VAS scale

4**Description**

Wound healing

Timepoint

Weekly follow up till 2 months

Method of measurement

Physical examination by 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 (Sitting in warm water, using laxative and stool bulking twice a day with plain olive oil ointment)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Amin Dalili

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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

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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 updating data

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable