

# 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

##### Street address

Ibn-e-Sina St, Imam Reza Hospital

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

009851

##### Phone

+98 51 3852 5255

##### Email

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.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

009851

##### Phone

+98 51 3841 1538

##### Email

vcresearch@mums.ac.ir

##### 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

##### Street address

Surgical Oncology Research Center, Imam Reza Hospital, Mashhad University of Medical Sciences

##### City

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##### Province

Razavi Khorasan

##### Postal code

009851

##### Phone

+98 51 3180 2557

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Amin Dalili

##### Position

Asistant professor

##### Latest degree

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##### Other areas of specialty/work

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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