

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### The use of silver nitrate and platelet fibrin glue in the treatment of anal fistulas

#### Protocol summary

##### Study aim

Determining the effect of using silver nitrate and platelet fibrin glue in the treatment of anal fistulas

##### Design

A non-randomized, uncontrolled, single clinical trial will be conducted in phase 2 on 10 patients.

##### Settings and conduct

Imam Reza and Qaim Hospital

##### Participants/Inclusion and exclusion criteria

1. Patients who have a perianal fistula resistant to surgical treatment as diagnosed by a medical specialist;
2. Patients should be over 18 years old;
3. Obtain written consent
4. Patients who, in addition to anal fistula, have other urinary fistulas/active infection/carcinoma in situ/tumor will not be included in the study.

##### Intervention groups

The intervention group includes individuals with perianal fistula resistant to surgical treatment. In the operating room, 2 ml of 10% silver nitrate will first be injected into their perianal fistula channel. Then 5 ml of platelet-rich fibrin glue will also be injected into the fistula.

##### Main outcome variables

Reepithelialisation and fistula closure; The disappearance of evidence of discharge and inflammation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191228045924N4**

Registration date: **2023-03-25, 1402/01/05**

Registration timing: **prospective**

Last update: **2023-03-25, 1402/01/05**

Update count: **0**

##### Registration date

2023-03-25, 1402/01/05

##### Registrant information

###### Name

Daryoush Hamidi Alamdari

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3882 8574

###### Email address

hamidiad@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-21, 1402/02/01

##### Expected recruitment end date

2023-10-23, 1402/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The use of silver nitrate and platelet fibrin glue in the treatment of anal fistulas

##### Public title

Investigating the effect of using silver nitrate and platelet fibrin glue in the treatment of anal fistulas

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Patients who have a perianal fistula resistant to surgical treatment as diagnosed by a medical specialist Patients should be over 18 years old Obtain written consent

**Exclusion criteria:**

Patients who, in addition to anal fistula, have other urinary fistulas/active infection/carcinoma in situ/tumor.

**Age**

From **18 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **10**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics committees of Mashhad University of Medical Sciences

**Street address**

Daneshgah street, the central organization of University, Quraishi construction

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Approval date**

2023-03-04, 1401/12/13

**Ethics committee reference number**

IR.MUMS.REC.1401.405

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

Anal fistula

**ICD-10 code**

K60.3

**ICD-10 code description**

Anal fistula

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

discharge amount

**Timepoint**

Before the intervention and after the intervention every 24 hours

**Method of measurement**

By visual observation of the dressing that is placed on the fistula site

**2****Description**

The duration of recovery, which is the number of days it takes for the discharge from the fistula to stop.

**Timepoint**

Every 24 hours (every day)

**Method of measurement**

By visual observation of the dressing that is placed on the fistula site

**3****Description**

Presence of inflammation and infection

**Timepoint**

Before the intervention and after the intervention every week for one month

**Method of measurement**

Clinical examination

**Secondary outcomes****1****Description**

Reepithelialisation and fistula closure

**Timepoint**

During the 6-month follow-up period of the patient

**Method of measurement**

clinical examination

**Intervention groups****1****Description**

The intervention group includes individuals with perianal fistula resistant to surgical treatment. In the operating room, 2 ml of 10% silver nitrate will first be injected into their perianal fistula channel. Then 5 ml of platelet-rich fibrin glue will also be injected into the fistula.

**Category**

Treatment - Drugs

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Imam Reza Hospital

**Full name of responsible person**

Amin Dalili

**Street address**

Iman Reza Hospital, Daneshgah Ave

**City**

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9137913316

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+98 51 3854 3031

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DaliliAM@mums.ac.ir

## 2

### Recruitment center

**Name of recruitment center**

Qaim Hospital

**Full name of responsible person**

Zahra Gholami Moalem

**Street address**

Ghaem Hospital, Ahmadabad Blvd

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gholamidr1@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Majid Ghayour Mobarhan

**Street address**

Daneshgah Street, Central Organization of University,  
Qurashi Building

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presidentoffice@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**

Daryoush Hamidi Alamdari

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Biochemistry

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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Mashhad University of Medical Sciences  
**Full name of responsible person**  
Daryoush Hamidi Alamdari  
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Associate professor  
**Latest degree**  
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**Other areas of specialty/work**  
Biochemistry  
**Street address**  
Surgical Oncology Research Center, Mashhad  
University of Medical Sciences, General Surgery  
Department, Building No. 2, Imam Reza hospital  
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**Province**  
Razavi Khorasan  
**Postal code**  
9133913716  
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+98 51 3854 3031  
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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

Yes - There is a plan to make this available

### Statistical Analysis Plan

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

### Informed Consent Form

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

### Clinical Study Report

Yes - There is 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

### Title and more details about the data/document

All data related to the project after the unidentifiable people will be shared.

### When the data will become available and for how long

Access to data is allowed 6 months after the publication of results.

### To whom data/document is available

Our data will be available for university staff and academic institutions

### Under which criteria data/document could be used

According to the policies of the journal in which the article will be published, the data will be made available.

### From where data/document is obtainable

The corresponding author of the article

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

The request should be sent by email to the corresponding author and he will respond as soon as possible after reviewing the request.

### Comments