Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Iran (Islamic Republic of)
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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
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2

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Daryoush Hamidi Alamdari
Position
Associate professor
Latest degree
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Other areas of specialty/work
Biochemistry
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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
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