

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of Internal Sphincterotomy and Medical Treatment with Aloe vera Gel in Chronic Anal Fissure

Protocol summary

Study aim

Comparison of internal sphincterotomy and medical treatment with Aloe vera gel in chronic anal fissure

Design

Two arm parallel group randomised trial

Settings and conduct

In this clinical trial, 50 patients who will be scheduled for chronic anal fissure in Velayat hospital of Qazvin will be randomly divided in 2 equal 25 patient group. All patients will be notified about treatment conditions and consent form will be obtained. In group A, surgical and routine care is performed, and in group B, the Alveolar gel is used three times a day. All patients are examined within two, four and six weeks after treatment, and they are assessed for itching, pain, bleeding and wound healing.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with chronic fissure that require treatment. Exclusion criteria : patients with Diabetes; Crohn's disease; Ulcerative colitis; Cancer and Pregnancy.

Intervention groups

Treatment group with internal sphincterotomy and medical treatment group with Aloe vera gel

Main outcome variables

Comparison of internal sphincterotomy and medical treatment with Aloe vera gel in itching of chronic anal fissure. Comparison of internal sphincterotomy and medical treatment with Aloe vera gel in bleeding of chronic anal fissure. Comparison of internal sphincterotomy and medical treatment with Aloe vera gel in the pain of chronic anal fissure. Comparison of internal sphincterotomy and medical treatment with Aloe vera gel in wound healing of chronic anal fissure.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190430043425N1**

Registration date: **2019-05-16, 1398/02/26**

Registration timing: **prospective**

Last update: **2019-05-16, 1398/02/26**

Update count: **0**

Registration date

2019-05-16, 1398/02/26

Registrant information

Name

Davoud Karimzadeh Aghda

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3379 0620

Email address

davoud.karim65@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Internal Sphincterotomy and Medical Treatment with Aloe vera Gel in Chronic Anal Fissure

Public title

Medical Treatment with Aloe vera Gel in Chronic Anal Fissure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with chronic fissure that require treatment.

Exclusion criteria:

Diabetes Crohn's disease Ulcerative colitis Cancer

Pregnancy

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization with Win Pepi

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Shahid Bahonar Blvd, Vice chancellor for research

City

Qazvin

Province

Qazvin

Postal code

3419915315

Approval date

2018-11-20, 1397/08/29

Ethics committee reference number

IR.QUMS.REC.1397.203

Health conditions studied

1

Description of health condition studied

Chronic anal fissure

ICD-10 code

K60.1

ICD-10 code description

Chronic anal fissure

Primary outcomes

1

Description

Comparison of internal sphincterotomy and medical treatment with Aloe vera gel in itching of chronic anal fissure

Timepoint

Two, four and six weeks after treatment

Method of measurement

The itching score is defined from 0 lack of itching up to 4 very severe itching.

2

Description

Comparison of internal sphincterotomy and medical treatment with Aloe vera gel in bleeding of chronic anal fissure

Timepoint

Two, four and six weeks after treatment

Method of measurement

Permanent bleeding after defecation means high bleeding, bleeding occasionally during defecation means middle bleeding and the presence of thin transparent blood without bleeding during defecation means that the bleeding is low and the absence of bleeding, for at least 5 days, means no bleeding.

3

Description

Comparison of internal sphincterotomy and medical treatment with Aloe vera gel in the pain of chronic anal fissure

Timepoint

Two, four and six weeks after treatment

Method of measurement

The complete absence of pain means relief in pain and having any rate of pain means no relief in pain.

4

Description

Comparison of internal sphincterotomy and medical treatment with Aloe vera gel in wound healing of chronic anal fissure

Timepoint

Two, four and six weeks after treatment

Method of measurement

Full recovery of wound means anoderm healing without scarring and inflammation, relative healing of the wound means reducing inflammation and swelling of the wound,

lack of wound healing means remaining the wound or worsening as abscess or fistula.

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Internal sphincterotomy. This method is an operation performed on the internal anal sphincter muscle. The procedure helps by lowering the resting pressure of the internal anal sphincter, which improves blood supply to the fissure and allows faster healing.

Category

Treatment - Surgery

2

Description

Intervention group: Medical treatment with Aloe vera gel. Aloe vera gel as much as a knuckle three times a day.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Educational and Treatment Center

Full name of responsible person

Davoud Karimzade Aghda

Street address

Taavon Square, 22 Bahman Blvd, Minoodar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Amir Peymani

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Davoud Karimzadeh Aghda

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

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Position

Assistant Professor

Latest degree

Specialist

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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

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

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

Person responsible for updating data**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Davoud Karimzadeh Aghda

Position

Resident

Latest degree

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Other areas of specialty/work

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