Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

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

Protocol summary

Study aim
Comparison of internal sphincterotomy and medical treatment with Aloevera gel in chronic anal fissure

Design
Two arm parallel group randomised trial

Settings and conduct
In this clinical trail, 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 Aloevera gel

Main outcome variables
Comparison of internal sphincterotomy and medical treatment with Aloevera gel in itching of chronic anal fissure. Comparison of internal sphincterotomy and medical treatment with Aloevera gel in bleeding of chronic anal fissure. Comparison of internal sphincterotomy and medical treatment with Aloevera gel in the pain of chronic anal fissure. Comparison of internal sphincterotomy and medical treatment with Aloevera 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)

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+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 Aloevera Gel in Chronic Anal Fissure

Public title

Medical Treatment with Aloevera 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 Aloevera 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 Aloevera gel in bleeding of chronic anal fissure

Timepoint
Two, four and six weeks after treatment

Method of measurement
Permanent bleeding after defication means high bleeding, bleeding occasionally during defication means middle bleeding and the presence of thin transparent blood without bleeding during defication 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 Aloevera 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 Aloevera 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 Aloevera gel. Aloevera 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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Phone
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Email
info@qums.ac.ir
Web page address
https://www.qums.ac.ir

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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Shahid Bahonar Blvd
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Email
info@qums.ac.ir
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
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Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
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Full name of responsible person
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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
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