

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Clinical trial Study of the effect of Myrtoid and 2% diltiazem with placebo in treatment of complications of chronic anal fissure patients

Protocol summary

Study aim

1- Comparison of the Effect of Myrtoid and 2% diltiazem with placebo in treatment of pain of chronic anal fissure patients
2- Comparison of the effect of Myrtoid and 2% diltiazem with placebo in treatment of itching of chronic anal fissure patients

Design

Clinical trials with a community-based and pragmatic control group with parallel, randomized groups, Group 1: Plasma suppository treatment, Group 2: Treatment with diltiazem gel 2%, Group 3: Treatment with Myrtoid suppository, randomization method Simple randomization, randomization unit: individual, randomization tool: random number table, the triple blinded, The total sample size of 99 patients with at least 2 months of a chronic anal fissure in 3 groups, clinical trial phase: 3.

Settings and conduct

Chronic anal fissure is a common anorectal disease that presents with pain and bleeding during bowel movements. Pain, spasm and ischemic injuries caused by improper repair become a fissure to be chronic from. This study aimed to compare the effects of Myrtoid and 2% diltiazem with placebo in treatment of patients of chronic anal fissure . Patients referred to the Baqiyatallah hospital who were diagnosed with at least 2 months of chronic anal fissure. In this study, the patients, measuring the outcomes of study participants (researchers) or Data Monitoring Committee (analyzers) of the patients unaware about intervention. Clinical trials with a community-based and pragmatic control group with parallel, randomized groups, Group 1: Plasma suppository treatment, Group 2: Treatment with diltiazem gel 2%, Group 3: Treatment with Myrtoid suppository, randomization method Simple randomization, randomization unit: individual, randomization tool: random number table, the triple blinded, The total sample size of 99 patients with at least 2 months of a chronic anal fissure in 3 groups, clinical

trial phase: 3.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having at least 2 months of chronic anal fissure
Exclusion criteria: Patients with Crohn's disease, patients with colon cancer, patients with diabetes, history of anal surgery

Intervention groups

Group 1: Plasma plus suppository, Group 2: Treatment with diltiazem gel 2%, Group 3: Treatment with Myrtoid suppository

Main outcome variables

Pain, Itching

General information

Reason for update

Acronym

اثير ميرتوييد با ديلتيازيم 2% و پلاسيبو در درمان عوارض بيماران با فيشرآنال مزمن

IRCT registration information

IRCT registration number: **IRCT20160914029818N3**
Registration date: **2018-01-27, 1396/11/07**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-27, 1396/11/07**

Update count: **0**

Registration date

2018-01-27, 1396/11/07

Registrant information

Name

Shahram Manoochehry

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8805 3766

Email address

shahram.manoochehry@bmsu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-04-09, 1396/01/20

Expected recruitment end date
2018-02-20, 1396/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial Study of the effect of Myrtoïd and 2% diltiazem with placebo in treatment of complications of chronic anal fissure patients

Public title
The effect of Myrtoïd and 2% diltiazem with placebo in treatment of complications of chronic anal fissure patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having at least 2 months of chronic anal fissure

Exclusion criteria:

Patients with Crohn's disease Patients with colon cancer

Patients with diabetes History of anal surgery

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **99**

Actual sample size reached: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization, randomization unit: individual, randomization tool: random number table, there is not allocation concealment.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, the patients, measuring the outcomes of study participants (researchers) or Data Monitoring Committee (analyzers) of the patients unaware about intervention.

Placebo

Used

Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiyatallah University of Medical Sciences

Street address

Postal code: 1435917541, Mollasadra, St - Sheikh Bahaee, St, Tehran

City

Tehran

Province

Tehran

Postal code

1435917541

Approval date

2017-06-02, 1396/03/12

Ethics committee reference number

IR.Bmsu.rec.1396.3

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

Pain

Timepoint

Two weeks after treatment

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Itching

Timepoint

Two weeks after treatment

Method of measurement

Questionnaires with Likert scale (low, medium and high)

Intervention groups

1

Description

Intervention group: Myrtoid

Category

Treatment - Drugs

2

Description

Intervention group: 2% diltiazem

Category

Treatment - Drugs

3

Description

Control group: Suppository placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Surgery Department of Baqiyatallah hospital

Full name of responsible person

Sahram Manoochehry

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Postal code: 1435917541, Mollasadra Street, Sheikh Bahaee St, Tehran

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Phone

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Email

shahram.manoochehry@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Hamid Reza Rasouli

Street address

Postal code: 1435917541, Mollasadra Street, Sheikh Bahaee Street, Tehran

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hr.rasouli64@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Shahram Manoochehry

Position

Faculty member/General surgery

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

Clinical trial Study of the effect of Myrtoid and 2% diltiazem with placebo in treatment of complications of chronic anal fissure patients

When the data will become available and for how long

In 2018

To whom data/document is available

Shahram Manoochehry

Under which criteria data/document could be used

Analysis

From where data/document is obtainable

Shahram Manoochehry

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

Publish in journal

Comments