Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

اثیر میرتویید با دیلتیازم 2% و پلاسیبو در درمان عوارض بیماران با فیشرآنال 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
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Iran (Islamic Republic of)
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+98 21 8805 3766
Email address
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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 Myrtoid and 2% diltiazem with placebo in treatment of complications of chronic anal fissure patients

Public title
The effect of Myrtoid 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 traetment
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 placepo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Surgery Department of Baqiyatallah hospital
Full name of responsible person
Sahram Manoochehry
Street address
Postal code: 1435917541, Mollasadra Street, Sheikh Bahaee St, Tehran
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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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+98 21 8805 3766
Email
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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Person responsible for updating data

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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