

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Evaluation of the efficacy of topical hydrocortisone in the treatment of rectal fissure in patients undergoing pharmacological treatment referred to Fatemi Hospital

Protocol summary

Study aim

Determining the effectiveness of topical hydrocortisone in the treatment of anal fissures in patients undergoing drug treatment referred to the clinic of Fatemi Hospital and Kosar Clinic of Ardabil Medical Sciences

Design

The sample size will be 200 people, which will be in two parallel groups of 100 people. There is no randomization in the study. Blindness has not been observed. The study is in the third phase of clinical trial.

Settings and conduct

The study will be conducted in the clinic of Fatemi Hospital and Kosar Clinic of Ardabil Medical Sciences. 200 patients will be included in the study. In the first group, routine treatment and in the second group, in addition to routine treatment, hydrocortisone ointment will be prescribed. Correction and randomization in the study have not been observed.

Participants/Inclusion and exclusion criteria

Including criteria: Patients with chronic anal fissures
Age 15 to 40 years
Excluding criteria: • Addiction to any drug • History of pre-anal surgery • Existence of simultaneous hemorrhoids • Acute fissures • Any Fisher's symptoms in diseases such as Crohn's or tuberculosis or malignancy • People with Crohn's disease • People with ulcerative colitis • Patients with hypothyroidism

Intervention groups

Intervention Group 1: This group includes 100 patients with chronic Fisher's disease. For 3 months, these patients are treated with Diltiazem 2.% pea gel about half a gram every 8 hours, psyllium powder is dissolved in a glass of water and consumed every morning. Lactulose 5 cc syrup every 8 hours. 1% topical hydrocortisone topical ointment made by Abu Reihan Company will consume the size of a pea weighing approximately 0.35 grams every 8 hours. The second intervention group is exactly the same as the first

intervention group, except that it will not be prescribed hydrocortisone.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191224045888N1**

Registration date: **2020-05-29, 1399/03/09**

Registration timing: **retrospective**

Last update: **2020-05-29, 1399/03/09**

Update count: **0**

Registration date

2020-05-29, 1399/03/09

Registrant information

Name

Mir Salim Seyd Sadegi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3323 0739

Email address

m.notash@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

2018-09-23, 1397/07/01
Actual recruitment end date
2019-08-21, 1398/05/30
Trial completion date
2019-08-21, 1398/05/30

Scientific title

Evaluation of the efficacy of topical hydrocortisone in the treatment of rectal fissure in patients undergoing pharmacological treatment referred to Fatemi Hospital

Public title

The effect of topical hydrocortisone in the treatment of anal fissure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chronic Anal Fissure

Exclusion criteria:

Any drug addiction Peri anal surgery history Hemorrhoids at the same time Acute Fissure Patients with Crohn's disease Patients with ulcerative colitis Patients with hypothyroidism

Age

From **15 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **200**

Actual sample size reached: **200**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary outcomes

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

No. 1, Daneshgah Ave

City

Ardabil

Province

Ardabil

Postal code

5613874595

Approval date

2020-04-11, 1399/01/23

Ethics committee reference number

IR.ARUMS.REC.1399.027

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 scale

Timepoint

On first visit, 2 weeks later, 6 weeks later, 3 months later

Method of measurement

NRS (numerical rating scale) questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1: This group includes 100 patients with chronic Fisher's disease. For 3 months, these patients are treated with Diltiazem 2% made by sobhan company pea gel about half a gram every 8 hours, psyllium powder made by poorsina company is dissolved in a glass of water and consumed every morning. Lactulose 5 cc syrup made by emad darman pars every 8 hours. 1% topical hydrocortisone topical ointment made by Abu Reihan Company will consume the size of a pea weighing approximately 0.35 grams every 8 hours. The second intervention group is exactly the same as the first intervention group, except that it will not be prescribed hydrocortisone.

Category

Treatment - Drugs

2

Description

Intervention group 2: This group includes 100 patients with chronic Fisher's disease. This group is treated

exactly with the drugs of the first group, except that they will not receive hydrocortisone.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center**Name of recruitment center**

Fatemi hospital

Full name of responsible person

Dr Mahdi Notash

Street address

No. 1, Emam khomeyni Ave.

City

Ardabil

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5613843793

Phone

+98 45 3323 0739

Email

m.notash@arums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

Parvaneh Naftchi

Street address

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56138745852

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meisamfooladi@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ardabil 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**

Ardabil University of Medical Sciences

Full name of responsible person

Mahdi Notash

Position

Resident General Surgery

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Mahdi Notash

Position

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Latest degree

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

Ardabil University of Medical Sciences

Full name of responsible person

Mahdi Notash

Position

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Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Email

meisamfooladi@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The questionnaires will be made available anonymously and with a file number.

When the data will become available and for how long

After completing the study

To whom data/document is available

University professors

Under which criteria data/document could be used

En In order to find out how to work in SPSS file, anonymous questionnaires will only be available with file number.

From where data/document is obtainable

Contact Dr. Mahdi Notash

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

Information is available after contacting Dr. Mahdi Notash and University approval

Comments