

# 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

**Province**

Ardabil

**Postal code**

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**

No. 1, Daneshgah Ave

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**Province**

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**Postal code**

56138745852

**Phone**

+98 45 3323 0739

**Email**

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**

No. 1, Emam khomeyni Ave.

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**Postal code**

5613843789

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meisamfooladi@gmail.com

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

Ardabil University of Medical Sciences

**Full name of responsible person**

Mahdi Notash

**Position**

Resident General Surgery

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Medical doctor

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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**

Resident General Surgery

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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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**