# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

27 May 2026

## Evaluation of the effect of Glycerin suppository application in patients with Chronic anal fissure

## Protocol summary

**Study aim**
Determining the effect of glycerin suppository administration in patients with chronic anal fissure referred to Alzahra Hospital clinic in 2021

**Design**
Clinical trial with control group, with parallel groups, single blinded, randomized, on 120 patients Stratified randomization will be done through randomization software

**Settings and conduct**
Study is single-blind.Patients are randomly divided into 2groups of 60. treatment,in the controls is using a topical combination of lidocaine ointment and 2% diltiazem q8hr,and in the interventions is in the form of pediatric glycerin suppository(1gr)5 minutes after using lidocaine ointment and diltiazem every morning .The use of lidocaine and diltiazem ointment the same as the controls q8hr. Patients are visited 3 times and the information is recorded in a serial examination based on a checklist after treatment;Then visited again after three months.

**Participants/Inclusion and exclusion criteria**
Inclusion crteria:posterior or anterior fisher history of autoimmune disease,Immunity dificiency disease and previous gastrointestinal cancer,people over 40 years or positive family history of GI cancer with a normal colonoscopy؛no weight loss in the last 6 months and anorexia.With a positive FIT result or iron deficiency anemia,patient can be included in the study if colonoscopy and endoscopy are normal.Not entering :unwillingness to continue treatment؛smoking and spicy spices

**Intervention groups**
Treatment in the control:a topical combination of lidocaine ointment and diltiazem 2% q8hr.In the intervention:administration of pediatric glycerin suppository(1g) 5 minutes after using lidocaine ointment and diltiazem every morning, then the combination of lidocaine and diltiazem q8hr

**Main outcome variables**
Reduction of requiring surgery in patients with chronic anal fissure؛ Prevention of surgery complications including gas and stool incontinence and anal stenosis

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20210717051915N1**
Registration date: **2021-07-31, 1400/05/09**
Registration timing: **prospective**

Last update: **2021-07-31, 1400/05/09**
Update count: **0**

**Registration date**
2021-07-31, 1400/05/09

**Registrant information**
**Name**
Mohammad Eslamian
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 31 3620 1995
**Email address**
nazi.raees@yahoo.com

**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2021-09-23, 1400/07/01
**Expected recruitment end date**
2022-10-22, 1401/07/30
**Actual recruitment start date**
empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Evaluation of the effect of Glycerin suppository application in patients with Chronic anal fissure

**Public title**
Evaluation of the effect of Glycerin suppository on anal fissure healing
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Posterior or anterior fissure No previous history of autoimmune disease No history of immunodeficiency disease No history of previous gastrointestinal cancer People over 40 years of age with normal colonoscopy No risk factor including weight loss during 6 Last month No anorexia No history of gastrointestinal genetic cancers (such as FAP, HNPCC) If a person is positive with FIT or a person with iron deficiency anemia, if he has a normal colonoscopy and endoscopy can be included in the study
**Exclusion criteria:**
Reluctance to continue treatment smoking and spicy spices
**Age**
No age limit
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **120**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Patients with eligibility; After obtaining informed consent, are divided into two groups (control and intervention) through randomization software, and since we want the percentage of alcoholism to be the same in both groups, at the time of randomization, alcoholism is considered as a category. And we will use stratified randomization and finally 60 patients will be evaluated in each group.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
In this study, blinding is done and it is a single-blinded (the person who fills in the questionnaire
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Research Ethics Committees of Isfahan University of Medical Sciences
**Street address**
Deputy of Research and Technology- Building No. 4, Isfahan University of Medical Sciences and Health Services, Hezar Jerib St.
**City**
Isfahan
**Province**
Isfehan
**Postal code**
**Approval date**
2021-07-16, 1400/04/25
**Ethics committee reference number**
IR.MUI.MED.REC.1400.315

## 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**
1) Patients' pain score 2) Percentage of constipation improvement in the intervention group 3) Percentage of bleeding improvement in the intervention group 4) Percentage of improvement of incomplete stool discharge in the intervention group 5) Percentage of burning sensation in the intervention group 6) Percentage of itching improvement in the intervention group
**Timepoint**
1) Pain score of the intervention group with the control group before and after treatment (first day, second weekend, fourth weekend) 2) constipation of the intervention group and control group (first day, second weekend, fourth weekend) 3) bleeding Intervention group and control group (first day, second weekend, fourth weekend) 4) incomplete defecation of the intervention group and control group (first day, second weekend, fourth weekend) 5) burning of the intervention group and control group (first day , Second weekend, fourth weekend) 6) itching Intervention and control

group (first day, second weekend, fourth weekend)

**Method of measurement**

1) Measuring pain through Visual Analogue Scale 2) Percentage of improvement of constipation through checklist 3) Percentage of improvement of bleeding through checklist 4) Percentage of improvement of incomplete stool discharge through checklist 5) Percentage of improvement of burning through checklist 6) Percentage of itching recovery through checklist

## Secondary outcomes

### 1

**Description**

1) Headache improvement 2) Quality of life indicators score

**Timepoint**

1) Improvement of headache after treatment (second weekend, fourth weekend) 2) score of quality of life indicators before and after treatment (first day, second weekend, fourth weekend)

**Method of measurement**

1) Improvement of headache through a checklist 2) Score of quality of life indicators based on WHO-QOL 100 questionnaire

## Intervention groups

### 1

**Description**

Intervention group: treatment is in the form of pediatric glycerin suppository 1 g, 5 minutes after using lidocaine ointment and diltiazem every morning, and the use of lidocaine and diltiazem ointment is the same as the control group every 8 hours during the day; Some lubricant gel can be impregnated around the suppository to facilitate passage. Iran Najo Pharmaceutical Co. Tehran-Iran

**Category**

Treatment - Drugs

### 2

**Description**

Control group: Treatment of fissure in this group is using a topical combination of lidocaine ointment and diltiazem 2% every 8 hours.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Isfahan Al-Zahra hospital clinic

**Full name of responsible person**

Mohammad Eslamian

**Street address**

Al-Zahra University Hospital, Soffe Blvd

**City**

Isfahan

**Province**

Isfehan

**Postal code**

81746 75731

**Phone**

+98 31 3620 2020

**Email**

nazi.raees@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Isfahan University of Medical Science

**Street address**

Isfahan University of Medical Sciences and Health Services, Hezar Jerib St

**City**

Isfahan

**Province**

Isfehan

**Postal code**

81746-73461

**Phone**

+98 31 3792 3071

**Email**

nazi.raees@yahoo.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mohammad Eslamin

**Position**

Associate professor

**Latest degree**
Specialist
**Other areas of specialty/work**
General Surgery
**Street address**
Al-Zahra University Hospital, Soffe Blvd
**City**
Isfahan
**Province**
Isfehan
**Postal code**
81746 75731
**Phone**
+98 31 3620 2020
**Email**
mr.esl67@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Mohammad Eslamian
**Position**
Associate professor
**Latest degree**
Specialist
**Other areas of specialty/work**
General Surgery
**Street address**
Al-Zahra University Hospita, Soffe Blvd
**City**
Isfahan
**Province**
Isfehan
**Postal code**
81746 75731
**Phone**
+98 31 3620 2020
**Email**
mr.esl67@gmail.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Mohammad Eslamian
**Position**
Associate professor
**Latest degree**
Specialist
**Other areas of specialty/work**
General Surgery
**Street address**
Al-Zahra University Hospital, Soffe Blvd
**City**
Isfahan
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**Postal code**
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## 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**
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**
Information on the complications of the disease before treatment and changes after treatment can be shared.
**When the data will become available and for how long**
four months after the end of the clinical trial (February 2021)
**To whom data/document is available**
Researchers working in academic and scientific institutions
**Under which criteria data/document could be used**
According to the statistical analyzes, the data are evaluated and in case of positive results, this new treatment and intervention can be used as a new treatment and reduction of complications from previous treatments such as surgery in patients with chronic anal fissure.
**From where data/document is obtainable**
Dr. Mohammad Islamian - General Surgeon - Isfahan University of Medical Sciences- mr.esl67@gmail.com
**What processes are involved for a request to access data/document**
After the trial, the data are processed and reported within one to two months, depending on the type of variables and the type of statistical analysis, with the cooperation of a statistical consultant
**Comments**
The course of future releases will be announced in more detail