

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### comparison of the effectiveness topical diltiazem and nifedipin in improving symptom and healing in patient with acute fissure

#### Protocol summary

##### Study aim

Comparison of the effectiveness topical diltiazem and nifedipin in improving symptom and healing in patient with acute fissure

##### Design

This study was designed as a single-blinded randomized clinical trial with parallel groups and a sample size of 70 people in each group

##### Settings and conduct

The study will be conducted at Ziaeeian Hospital on patients with acute fissure. Patients who signed informed consent will be randomly divided into two groups. The first group will receive 0.3% nifedipine ointment (Synthesized in the pharmacy of Razi Hospital affiliated to Tehran University of Medical Sciences), Peri-anally, three times a day, quantity of a knuckle for 2 months. The Group-B will be treated by 2% diltiazem ointment (Sobhan Company) Peri-anally, three times a day, amount of a knuckle for 2 months. The final outcome of the study will be assessed by a third party who is unaware of the study process. Also, the statistician will be unaware of the study process

##### Participants/Inclusion and exclusion criteria

Conditions for entry over the age of 18, Acute fissure, exclusion criteria history of anal surgery, Anorectal malformation and pregnancy

##### Intervention groups

Group-A will receive 0.3% nifedipine ointment, Synthesized in the pharmacy of Razi Hospital affiliated to Tehran University of Medical Sciences, Peri-anally, three times a day, quantity of a knuckle for 2 months. Group-B will be treated by 2% diltiazem ointment (Sobhan Company) Peri-anally, three times a day, amount of a knuckle for 2 months

##### Main outcome variables

Duration of pain, healing and relapse of fissure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190414043275N1**

Registration date: **2021-07-05, 1400/04/14**

Registration timing: **prospective**

Last update: **2021-07-05, 1400/04/14**

Update count: **0**

##### Registration date

2021-07-05, 1400/04/14

##### Registrant information

##### Name

Zahra Momayez sanat

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8871 9645

##### Email address

z-msanat@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-07-22, 1400/04/31

##### Expected recruitment end date

2021-12-20, 1400/09/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

comparison of the effectiveness topical diltiazem and nifedipin in improving symptom and healing in patient with acute fissure

**Public title**

Diltiazem in fissure

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Acute fissure

**Exclusion criteria:**

Pregnancy history of anal surgery Anorectal malformation

**Age**

From **18 years** old

**Gender**

Both

**Phase**

4

**Groups that have been masked**

- Investigator

**Sample size**

Target sample size: **140**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization approach will be implemented in this study. Randomization will be performed using a computer-generated list. For this purpose, 140 sealed envelopes will be numbered 1-140 according to the randomization list. Group allocation will be kept separate until the study is completed. The randomization ratio would be 1: 1, with 70 envelopes allocated to each group

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Completion of the final information is up to the person who is unaware of the type of treatment and also the specialist will be blind. Due to the type of intervention, participants are aware of the type of treatment

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of tehran university of medical science

**Street address**

jalal al ahmad shariati hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713135

**Approval date**

2020-09-07, 1399/06/17

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1399.420

**Health conditions studied****1****Description of health condition studied**

Acute anal fissure

**ICD-10 code**

K60.0

**ICD-10 code description**

Acute anal fissure

**Primary outcomes****1****Description**

Duration of pain

**Timepoint**

Before the intervention, every week for up to 8 weeks after the intervention

**Method of measurement**

Question from the patient

**Secondary outcomes****1****Description**

healing of anal fissure

**Timepoint**

After two months of intervention

**Method of measurement**

Physical examination

**2****Description**

Relapse

**Timepoint**

6 months after intervention

**Method of measurement**

Question from the patient

**Intervention groups****1****Description**

Group-A will received 0.3% nifedipine ointment, Synthesized in the pharmacy of Razi Hospital affiliated to

Tehran University of Medical Sciences, Peri-anally , three times a day, quantity of a knuckle for 2 months

**Category**

Treatment - Drugs

**2**

**Description**

Group-B will treated by 2% diltiazem ointment (Sobhan Company) , Peri-anally , three times a day, amount of a knuckle for 2 months

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

zieaan

**Full name of responsible person**

zahra momayez sanat

**Street address**

jalal ale ahmad shariati hospital

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**Province**

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**Phone**

+98 21 84901

**Email**

msanat67@ gmail .com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

zhra momayz sanat

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jalale ale ahmad shariati hospital

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**Province**

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1411713135

**Phone**

+98 21 84901

**Email**

msanat67@ gmail.com

**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

private

**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**

Persons

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

zahra momayez sanat

**Position**

associated professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

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**Province**

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1411713135

**Phone**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

zahra momayez sanat

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associated professore

**Latest degree**

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

Tehran University of Medical Sciences

**Full name of responsible person**

zahra momayez sanat

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associated professore

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**Other areas of specialty/work**

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**Province**

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**Postal code**

1411713135

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be 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