

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of topical Nifedipine with oral Nifedipine for treatment of anal fissure: A randomized controlled trial

Protocol summary

Summary

Medical sphincterotomy has gained popularity as a treatment for anal fissure. Ca channel blockers in topical forms may be appropriate treatment with low adverse effect. This study designed for comparing topical and oral nifedipine in treatment of chronic anal fissure. Methods: A prospective randomized controlled trial was conducted on 60 patients in topical nifedipine (0.5%) and 59 patients in 10 mg/TDS oral nifedipine. Patients were assessed on regular visit for pain score, blood pressure, pulse rate, healing of ulcer bed and side effects. The ultimate follow up period was 6m.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104166200N1**
Registration date: **2012-11-16, 1391/08/26**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-11-16, 1391/08/26

Registrant information

Name

Farzaneh Golfam

Name of organization / entity

Shahed University, Medicine faculty

Country

Iran (Islamic Republic of)

Phone

+98 21 8896 9437

Email address

golfam@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

grant

Expected recruitment start date

2002-02-20, 1380/12/01

Expected recruitment end date

2007-02-20, 1385/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of topical Nifedipine with oral Nifedipine for treatment of anal fissure: A randomized controlled trial

Public title

The effect of Nifedipine for treatment of anal fissure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: chronic anal fissure patients. Exclusion criteria: patients had history of sexually transmitted disease, TB, IBD, or medically related conditions such as gestation, migraine, cardiovascular and other chronic diseases, anorectal surgery or another anorectal disease.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **119**

Randomization (investigator's opinion)

Randomized

Randomization description
Blinding (investigator's opinion)

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Medicine faculty of Shahed university

Street address

Ebadollah zade street, Keshavarz Blvd

City

Tehran

Postal code**Approval date**

2010-09-23, 1389/07/01

Ethics committee reference number

7

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**

ulcer healing in anal fissure

Timepoint

4 weeks (traetment period), 6 months (follow up)

Method of measurement

visual score

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

headache

Timepoint

2 months, 6 months

Method of measurement

visual, patient document

2**Description**

blood pressure and pulse rate

Timepoint

2 months, 6 months

Method of measurement

sphygnomanometer, physical exam, patient document

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

Nifedipine cream (0.5%) for 4 weeks

Category

Treatment - Drugs

2**Description**

10 mg of Nifedipine TDS for 4 weeks

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mostafa Khomeini Hospital

Full name of responsible person

Farzaneh Golfam

Street address

Italy street, Keshavarz BLVD

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahed Unniversity, Medicine faculty

Full name of responsible person

Marjan Heshmati

Street address

Shahid Ebadolahzade street, Keshavarz BLVD

City

Tehran

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

Yes

Title of funding source

Shahed Unniversity, Medicine faculty

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Shahed university

Full name of responsible person

Farzaneh Golfam

Position

Assistant Professor

Other areas of specialty/work**Street address**

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

Kermanshah University of Medical Sciences

Full name of responsible person

Parisa Golfam

Position

Assistant Professor of Anesthesiology

Other areas of specialty/work**Street address**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty