Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
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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 ducument

2

Description
blood pressure and pulse rate
Timepoint
2 months, 6 months
Method of measurement
sphygnomanometer, physical exam, patient ducument

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
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Italy street, Keshavarz BLVD
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahed Unniversity, Medicine faculty
Full name of responsible person
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Shahid Ebadolahzade street, Keshavarz BLVD
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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

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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