Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of topical nitroglycerin 0.2% with placebo on pain severity reduction in patients with proctalgia fugax

Protocol summary

Summary

Proctalgia fugax is an anorectal dysfunction characterized by severe, transient , repeated pain with irregular intervals in the anorectal region. Regarding the safety and being noninvasive administration of nitroglycerin among other medical treatments, the aim of this study was to evaluate the effectiveness of nitroglycerin on this disease. A total of 40 patients admitted to the GI clinic of Sanandaj randomly selected and using block method divided in 2 groups of 20 (each block was consisted of 4 people and totally 10 blocks). The intervention group received Nitroglycerin ointment 0.2% and control group received placebo. Drug and placebo were provided by the pharmacist and looks quite similar. Patients were given medication by a trained nurse. The patients as well as researchers were not aware of the type of ointment. Patients were told to use the ointment as much as a cherry core 3 times a day (every 8 hours) on pain site and intra anal for 2 weeks. Patients were assessed at the second week, three months and six months after starting treatment using post treatment questionnaire by treating physician. We defined a remarkable improvement if the number of episodes decreased to a half or the level of pain (according to the VPS) dropped by more than 50%.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122212789N12**
Registration date: **2016-02-08, 1394/11/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-08, 1394/11/19

Registrant information

Name

Masoud Rasolabady

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research,Kurdistan University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-12-21, 1394/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of topical nitroglycerin 0.2% with placebo on pain severity reduction in patients with proctalgia fugax

Public title

The effect of topical nitroglycerin 0.2% on anal pain reduction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria including: 1. Consent to participate in the study 2. Patients with recurrent episodes of severe pain localized in the lower rectum and anus area, and the

episodes of pain lasting a few seconds up to 20 minutes and there was no pain between episodes. Exclusion criteria including: 1. Any proved pathology during clinical history, physical examination and rectosigmoidoscopy in anorectal including (Hemorrhoids, ischemia, anal abscess, anal fissure, rectocele, malignancy, inflammation, anal prolapsed). 2. History of trauma, urinary tract infection, surgery and hysterectomy in recent 6 months 3. Associated symptoms (fever, change in stool consistency, anemia, anal secretions, abdominal pain, weight loss and rectal bleeding). 4. History of heart and neurological disease and aortic stenosis 5. History of hypotension 6. Chronic proctalgia 7. Unwillingness to continue participating in the study 8. Single rectal ulcer

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kurdistan University of Medical Sciences

Street address
Kurdistan University of Medical Sciences, Pasdaran St., Sanandaj, Iran

City
Sanandaj

Postal code

Approval date
2015-05-05, 1394/02/15

Ethics committee reference number
MUK.REC.1394.47

Health conditions studied

1

Description of health condition studied
Proctalgia fugax

ICD-10 code
K59.4

ICD-10 code description
Anal spasm

Primary outcomes

1

Description
Pain severity

Timepoint
The second week, three months and six months after treatment

Method of measurement
Visual Analog Scale

Secondary outcomes

1

Description
the repetition of pain

Timepoint
The second week, three months and six months after treatment

Method of measurement
questionnaire

Intervention groups

1

Description
Intervention Group: To use nitroglycerin 0.2% ointment as much as a cherry core 3 times a day (every 8 hours) on pain site and intra anal for 2 weeks.

Category
Treatment - Drugs

2

Description
Control Group: To use the eucerin (placebo) as much as a cherry core 3 times a day (every 8 hours) on pain site and intra anal for 2 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tohid Hospital

Full name of responsible person
Masomeh Allahmoradi

Street address
Tohid Hospital, Basij Sq., Geriashan St., Sanandaj, Iran
City
Sanandaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research ,Kurdistan University of Medical Sciences
Full name of responsible person
DR. Ebrahim Ghaderi
Street address
Kurdistan University of Medical Sciences, Pasdaran St., Sanandaj, Iran
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Sanandaj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research ,Kurdistan University of Medical Sciences
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
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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*