

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 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

Country

Iran (Islamic Republic of)

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Email address

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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****Name of organization / entity**

Kurdistan University of Medical Sciences

Full name of responsible person

Masomeh Allahmoradi

Position

Medical student

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

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Professor of Internal Medicine

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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

