Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of topical application of Nitroglycerin plus Diltiazem compared with the two methods of topical use of Bethanechol and Diltiazem in the treatment of patients with chronic anal fissure

Protocol summary

Summary

Objectives: Main objective: Comparison of the three types of medical treatment; Topical application of Nitroglycerin plus Diltiazem Gel , Bethanechol Gel and Diltiazem Gel in healing chronic anal fissure Secondary objectives: Record and assessment of pain and bleeding before, 4 and 8 weeks after treatment with the mentioned drugs Design: 90 patients with chronic anal fissure will be randomly divided into 3 groups: Group A: The recipient of combined therapy (1% Nitroglycerin cream plus 5% Diltiazem Gel as two separate products), Group B: Recipient of 5% Diltiazem Gel and Group C Receive 0.01% bethanechol Gel.Setting and conduct: The mentioned drugs will be taken topically three times a day for 8 weeks. After four and eight weeks patients will be examined for the condition of the healing, pain and bleeding. Inclusion and Exclusion criteria: Inclusion criteria: for this study does not consider specific criteria except having acute fissures. Exclusion criteria: pregnancy; Inflammatory bowel disease.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110130623N1**
Registration date: **2017-09-13, 1396/06/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-13, 1396/06/22

Registrant information

Name

Baran Parhizkar

Name of organization / entity

Kurdistan University of Medical scinces

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Kurdistan University of Medical Sciences

Expected recruitment start date

2016-10-21, 1395/07/30

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of topical application of Nitroglycerin plus Diltiazem compared with the two methods of topical use of Bethanechol and Diltiazem in the treatment of patients with chronic anal fissure

Public title

Comparison of the three types of medical treatment; Topical application of Nitroglycerin plus Diltiazem Gel , Bethanechol Gel and Diltiazem Gel in healing chronic anal fissure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: for this study does not consider specific criteria except having acute fissures. Exclusion Criteria: pregnancy; Inflammatory bowel disease; The incidence of side effects; Leave treatment; Colon cancer

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
A total of 90 patients were randomly divided into three groups of 30 subjects by blocking method. In order to blind the study, the drugs were given to patients by a nurse who was not sensitive to the results of the study. All of the patients' codes were kept by him until the data analysis phase, and the project executives were unaware of them until the end of the study Patients' visits were also carried out by a gastroenterologist who was not aware of the groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kurdistan university of medical sciences

Street address
Vice Chancellor for research of Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran.

City
sanandaj

Postal code

Approval date
2016-07-22, 1395/05/01

Ethics committee reference number
MUK.REC.1394.142

Health conditions studied

1

Description of health condition studied
chronic anal fissure

ICD-10 code
0,K60.1

ICD-10 code description
chronic anal fissure

Primary outcomes

1

Description
healing of fissure

Timepoint
Before intervention , 4 and 8 weeks after intervention

Method of measurement
Examination

Secondary outcomes

1

Description
bleeding

Timepoint
Before intervention, 4 and 8 weeks after intervention

Method of measurement
Examination and question from the patient

2

Description
Pain

Timepoint
Before intervention , 4 and 8 weeks after intervention

Method of measurement
Examination and question from the patient

Intervention groups

1

Description
Interventional group 1: Combination therapy (1% Nitroglycerine ointment plus topical 5% Diltiazem gel as separate product), TDS for eight weeks

Category
Treatment - Drugs

2

Description
Intervention group 2: bethanechol , 0.1% gel, topical, TDS for eight weeks

Category
Treatment - Drugs

3

Description

Control group: diltiazem, 5% gel, topical, TDS for eight weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology Clinic of Tohid Hospital

Full name of responsible person

Baran Parhizkar

Street address

Gastroenterology Clinic, Tohid Hospital, Geriashan Ave

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Kurdistan University of Medical Sciences

Full name of responsible person

Mastoureh Ostovar

Street address

Vice Chancellor for research of Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran.

City

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 of 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

Liver & Digestive Research center,Kurdistan university of medical sciences

Full name of responsible person

Baran Parhizkar

Position

Faculty Member

Other areas of specialty/work

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Position

Sub specialist of Gastroenterology and Hepatology

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Person responsible for updating data

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Name of organization / entity

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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