Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the effect of Sodium Pentaborate Topical Ointment on Anal fissure symptoms and treatment

Protocol summary

Study aim

Evaluation of the effect of Sodium Pentaborate Ointment on Anal fissure symptoms and treatment

Design

A randomized, double-blind, placebo-controlled phase 2_3 clinical trial with a parallel group on 140 patients.

Settings and conduct

This study is a double-blind, randomized, placebo-controlled study using Sodium Pentaborate or placebo ointment.The subjects are randomly assigned in a 2:1 ratio in intervention or control groups. Patients referred to the Gastroenterology clinics with signs and symptoms of anal fissure are included in the study or are excluded from the study through the entry/exit criteria and if informed consent is given. Blinding method: a gel that has an active ingredient in boron with a gel of placebo is completely identical in terms of the shape and size of the container, and the gels themselves do not differ in terms of odor and color. Identical tubes were labeled as A and B. In blinding, the physician, patient, data analyzer, and researcher will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Anal fissure that is detected in the perineal area by direct observation or rigid anoscopy or flexible colonoscopy- Exclusion criteria: Existence of any perineal complications including dermatitis, condyloma, hemorrhoids, anal abscess- Existence of lateral fissure- Patients with sodium pentaborate allergy- Pregnancy- being under the age of 18- Taking any topical anal medication during the last 7 days

Intervention groups

Intervention group: Topical ointment of 3% sodium pentaborate is applied to the wound for 14 days twice a day in the size of a fingertip Control group: These are the group that take placebo ointment that has no therapeutic properties.

Main outcome variables

Anal itching; Anal bleeding; Anal pain at rest; Anal pain during defecation Bleeding from the fissure during the examination; Pain at the Fissure site during the examination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190701044062N7**
Registration date: **2021-07-14, 1400/04/23**
Registration timing: **retrospective**

Last update: **2021-07-14, 1400/04/23**
Update count: **0**

Registration date

2021-07-14, 1400/04/23

Registrant information

Name

manouchehr khoshbaten

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 1334 3010

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-05, 1399/06/15

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

2020-09-05, 1399/06/15

Actual recruitment end date

2021-03-19, 1399/12/29

Trial completion date
2021-03-19, 1399/12/29

Scientific title
Evaluation of the effect of Sodium Pentaborate Topical Ointment on Anal fissure symptoms and treatment

Public title
The effect of Sodium Pentaborate In Anal fissure

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Chronic anal fissure that is detected in the perineal area by direct observation or rigid anoscopy or flexible colonoscopy.

Exclusion criteria:
Existence of any perineal complications including dermatitis, wart, condyloma, hemorrhoids, fistula, anal abscess 2. Proven Crohn's disease 3. Existence of lateral fissure 4. Patients with sodium pentaborate allergy 5. Pregnancy or breastfeeding 6. Patients with a history of serious cardiovascular, hepatic, renal and blood diseases 7. Taking any topical anal medication during the last 7 days 8. Prohibition of topical use of sodium pentaborate being under the age of 18

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **140**
Actual sample size reached: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
The block randomization method will be used to assign patients to the intervention and control groups with the ratio of 2 for sample size in intervention group to placebo group. The size of the blocks is 6. (Due to the difficulty in patient recruitment, we considered ratio of 2:1 for sample size in intervention group to placebo group to have more patients in intervention group). Randomization was performed using https://www.sealedenvelope.com/simple-randomiser/v1/lists [Accessed 11 Jul 2021]. Allocation concealment will be done using matte sealed envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
A gel that has an active ingredient in boron with a gel of placebo is completely identical in terms of the shape and size of the container, and the gels themselves do not differ in terms of odor and color, and are completely indistinguishable. (This action was taken by the pharmaceutical company). All ointments were either transparent and gelatinous and put in identical tubes by staff not involved further in the trial. Identical tubes were labeled as A and B. When the physician saw chronic anal fissure on anal examination and the patient has inclusion criteria of the study gave patients A code and B code tubes, respectively. In some hospitals, active molecules were put in A coded tube, and some hospitals in B coded tubes. The randomization codes remained in the pharmaceutical company staff who prepared the drug during the trial and was not available to the investigators. After collecting the data and completing the data analysis stage, the nature of the codes related to the groups will be revealed by the liaison person in the pharmaceutical company. The important point is that the patient is told that the gel used for the patient may be medication or medication. In blinding, the physician, patient, data analyzer, and researcher will be blind.

Placebo
Used

Assignment
Parallel

Other design features
ratio of 2 for sample size in intervention group to placebo group was considered and 129 patients (intervention group 86 cases, placebo group 43 cases) were needed to give a 80% chance of finding a 25% difference in healing between placebo and GTN at the 5% level. This number was increased by 10% to consider attrition or incomplete data. Finally, 140 cases (90 in intervention and 50 in placebo group) were recruited.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Central Office of Tabriz University of Medical Sciences Tabriz -Golghast St.- Azadi St.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2020-08-10, 1399/05/20

Ethics committee reference number
IR.TBZMED.REC.1399.512

Health conditions studied

1

Description of health condition studied
Anal fissure
ICD-10 code
K60.2
ICD-10 code description
Anal fissure, unspecified

Primary outcomes

1

Description
Anal itching
Timepoint
At the beginning of the study (before the intervention) and 14 days (2 weeks) after starting the ointment
Method of measurement
Ask the patient

2

Description
Anal bleeding
Timepoint
At the beginning of the study (before the intervention) and 14 days (2 weeks) after starting the ointment
Method of measurement
Ask the patient, inspection of anus and digital rectal examination

3

Description
Anal pain at rest
Timepoint
At the beginning of the study (before the intervention) and 14 days (2 weeks) after starting the ointment
Method of measurement
Ask the patient

4

Description
Anal pain during defecation
Timepoint
At the beginning of the study (before the intervention) and 14 days (2 weeks) after starting the ointment
Method of measurement
Ask the patient

5

Description
Bleeding from the fissure during the examination
Timepoint
At the beginning of the study (before the intervention) and 14 days (2 weeks) after starting the ointment
Method of measurement
Inspection of anus and digital rectal examination

6

Description
Pain at the Fissure site during the examination
Timepoint
At the beginning of the study (before the intervention) and 14 days (2 weeks) after starting the ointment
Method of measurement
Ask the patient, inspection of anus and digital rectal examination

Secondary outcomes

1

Description
Anal pain during defecation
Timepoint
At the beginning of the study (before the intervention) and 14 days (2 weeks) after starting the ointment
Method of measurement
Ask the patient

2

Description
Feeling of a mass around the anus
Timepoint
At the beginning of the study (before the intervention) and 14 days (2 weeks) after starting the ointment
Method of measurement
Ask the patient

Intervention groups

1

Description
Intervention group: Topical ointment of 3% sodium pentaborate, which is made under GLP and GMP conditions at Yeditpe University in Turkey and is applied to the wound for 14 days (2 weeks) twice a day in the size of a fingertip. The patient is taught for 15 to 30 minutes by an experienced and trained expert.
Category
Treatment - Drugs

2

Description
Control group: These are the group that take placebo ointment that has no therapeutic properties. It is worth mentioning that the participants in this project are patients with chronic anal fissure who have not previously responded to routine treatment (increased consumption of dietary fiber and nifedipine ointment) and for this reason, placebo was used for the control group. We remind you that according to the inclusion criteria, patients should not have used any topical anal drug for at least the last 7 days.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Gastroenterology and Endoscopy, Imam Reza Hospital, Tabriz

Full name of responsible person
Manouchehr Khoshbaten

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
A. Ghasem Jouyban

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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
Tabriz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Manouchehr Khoshbaten

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Part of the data, which includes information about the main outcome and results, will be shared.
When the data will become available and for how long
available from April 2021
To whom data/document is available
University researchers and professors
Under which criteria data/document could be used
The data will be available to researchers and university professors for the studies of the meta - analysis.
From where data/document is obtainable
Email: niloofarafshin1375@gmail.com نیلوفر افشین
What processes are involved for a request to access data/document
Request via email: niloofarafshin1375@gmail.com As soon as possible
Comments