Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of Sodium Pentaborate Topical Ointment on Hemorrhoid Symptoms

Protocol summary

Study aim

Evaluation of Sodium Pentaborate Topical Ointment on Hemorrhoid Symptoms

Design

To determine the sample size, the effect of sodium phentetraate ointment on improving the internal hemorrhoid grade 1 to 4 in patients with hemorrhoids was considered as the main objective. The basic information needed to calculate the sample size from Doğan et al. Was extracted in 2014. Using the G-Power software, with a 95% confidence interval, the test power of 80% and a 25% drop, the sample size was calculated to be 215, which will be performed in the study for the first time in patients with hemorrhoids, With a 50% sample rate (53 in each group).

Settings and conduct

This study is a double-blind, randomized, placebo-controlled study using sodium omeprazole or placebo ointment in people with symptomatic internal hemorrhoids. The subjects are randomly assigned in a 1: 1 ratio in intervention or control groups. Patients referred to the Hemorrhagic Clinic of Tabriz University of Medical Sciences with symptoms and symptoms of hemorrhoids are included in the study or are excluded from the study through the entry / exit criteria and if informed consent is given.

Participants/Inclusion and exclusion criteria

18-65 years old-Patients with hemorrhoids and with the diagnosis of internal hemorrhoid disease Grade I, II, III or IV. The presence of anal bleeding as one of the symptoms of a hemorrhoid in the patient- Non-use of a drug other than the drug and control drug for the treatment of hemorrhoids during the study period

Intervention groups

Intervention: 3% sodium pentahydrate Phenytoinate gel twice daily for 1 month Control: Treating patients with hemorrhoids in a way other than mentioned

Main outcome variables

Severity of itching-Severity of pain during rest - Severity of pain when starting the excretion of the stool - Frequency of sensation in the anus - Exhaustion of the hemorrhoid mass

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190701044062N1**
Registration date: **2019-07-13, 1398/04/22**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-13, 1398/04/22**
Update count: **0**

Registration date

2019-07-13, 1398/04/22

Registrant information

Name

manouchehr khoshbaten

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 1334 3010

Email address

mkhoshbaten@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-04, 1398/03/14

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Sodium Pentaborate Topical Ointment on Hemorrhoid Symptoms

Public title

Evaluation of Sodium Pentaborate Topical Ointment on Hemorrhoid Symptoms

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

65-18 years old Patients with hemorrhoids and those with I, II, III or IV internal hemorrhoid disorder without need for emergency interventions based on physical examination The presence of anal bleeding as one of the symptoms of a hemorrhoid in the patient (according to the Sodergren scoring system) Non-use of a drug other than the drug and control drug for the treatment of hemorrhoids during the study period

Exclusion criteria:

Disorders and analgesics including inflammatory bowel disease, Fisher, fistula and perianal rash, rectal prolapse, rectus, benign or malignant tumor of the anus and rectum, and perianal infections Patients with sodium phentetrazur susceptibility or a history of skin sensitivity to vaseline Pregnancy or breastfeeding Patients with severe heart disease, neurology, liver and kidney disease and blood diseases Taking any local analgesic for the past 7 days Prohibition of topical use of vaseline or sodium panteurate The history of permanent prolapse is the entire thickness of the rectum

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **53**

Randomization (investigator's opinion)

Randomized

Randomization description

Given the fact that the sample size is the same in both groups, we use the Excel software and the formula = Rand () to randomize and to increase the precision and balance of the samples in the randomization (for any reason Patient will withdraw from the plan) we use several blocks per group. It will also be provided to the physician to cover the allocation of matte envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

A gel that has an active ingredient in boron with a gel that does not have a substance and is used as a 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). The important point is that the patient is told that the gel used for the patient may be medication or medication. Clinicians and blind patients will be blinded.

Placebo

Used

Assignment

Parallel

Other design features

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

2019-06-03, 1398/03/13

Ethics committee reference number

IR.TBZMED.REC.1398.235

Health conditions studied

1

Description of health condition studied

Hemorrhoid

ICD-10 code

K64

ICD-10 code description

Hemorrhoids and perianal venous thrombosis

Primary outcomes

1

Description

Severe itching

Timepoint

25 to 30 days

Method of measurement

questionnaire and Sodergren Scoring System

2

Description
Severity of pain during rest
Timepoint
25 to 30 days
Method of measurement
Severity of pain during rest

3

Description
Pain intensity when starting fecal excretion
Timepoint
25 to 30 days
Method of measurement
Pain intensity when starting fecal excretion

4

Description
Frequent feeling of mass in the anus
Timepoint
25 to 30 days
Method of measurement
Frequent feeling of mass in the anus

5

Description
The severity of the outgrowth of the hemorrhoid mass
Timepoint
25 to 30 days
Method of measurement
Clinical evaluation

6

Description
The degree of anoscopic hemorrhoids
Timepoint
25 to 30 days
Method of measurement
Clinical evaluation

7

Description
Number of hemorrhoid hemorrhages
Timepoint
25 to 30 days
Method of measurement
Clinical evaluation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 3% sodium pentahydrate Phenytoinate gel twice daily for 1 month
Category
Treatment - Drugs

2

Description
Control group: Treating patients with hemorrhoids in a way other than the mentioned procedure
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
Street address
Golgasht St, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 1334 3010
Email
mkhoshbaten@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
A. Ghasem Jouyban
Street address
Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166/15731
Phone
+98 41 3335 9680
Email
research-vice@tbzmed.ac.ir
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
Adult digestive and liver

Street address
Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5166/15731

Phone
+98 41 3335 9680

Email
mkhoshbaten@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Manouchehr Khoshbaten

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Professor

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Phone
+98 41 1334 3010

Email
mkhoshbaten@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Manouchehr Khoshbaten

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Professor

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Email
mkhoshbaten@yahoo.com

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
A portion of the data will be shared.

When the data will become available and for how long
2020

To whom data/document is available
University researchers and professors

Under which criteria data/document could be used
For further studies

From where data/document is obtainable
by Email

What processes are involved for a request to access data/document
Request via email

Comments