Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Effect of a traditional preparation rectal suppository from Commiphora mukul (Hook. Ex Stocks) Engl. And Allium porrum L. on hemorrhoids in comparison with conventional anti-hemorrhoid suppository: A double-blind controlled trial

Protocol summary

Study aim
The aim of this study is to evaluate the therapeutic effect of a traditional rectal suppository containing Commiphora mukul (Hook. Ex Stocks) Engl. and Allium porrum L. in hemorrhoid.

Design
A clinical trial with an interventional and a control groups, double-blind, 80 patients, randomization by block randomization method.

Settings and conduct
In this study, patients were recruited at Shahid Rahnamon Hospital in Yazd. The doctor and patients are blinded in the study. The researcher provides the traditional rectal suppository and conventional anti-hemorrhoid suppository to the patient in sealed envelopes with a allocation concealment method, and the color and packaging of the both groups are completely similar.

Participants/Inclusion and exclusion criteria
Patients who suffer from hemorrhoids and dose not require emergency surgery with approval of a surgeon specialist are included in the study. The main exclusion criteria are other anorectal diseases (ex. fistula or anal cancer and perianal fissure), pregnancy and lactation.

Intervention groups
The patients are divided into two groups of 40 people randomly by block randomization method. The Colo-Rectal Evaluation of Clinical Therapeutics Scale (CORECTS) questionnaire and consent form completed by every patients. the Interventional group is taking a Traditional Rectal suppository and the control group Anti-hemorrhoid suppository. The medication in all two groups is taking a rectal suppository for two weeks, twice a day. After the end of the consumption period, the patient's symptoms are evaluated by the questionnaire.

Main outcome variables
Pain, itching, bleeding and swelling relief are evaluated according to the CORECTS questionnaire.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231224060516N1**
Registration date: **2024-01-23, 1402/11/03**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-23, 1402/11/03**
Update count: **0**

Registration date
2024-01-23, 1402/11/03

Registrant information

Name
Motahare Nayebzadeh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-20, 1402/10/30

Expected recruitment end date
2025-01-19, 1403/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of a traditional preparation rectal suppository from Commiphora mukul (Hook. Ex Stocks) Engl. And Allium porrum L. on hemorrhoids in comparison with conventional anti-hemorrhoid suppository: A double-blind controlled trial

Public title

Effect of traditional preparation rectal suppository in treatment of hemorrhoids

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Suffering from hemorrhoids based on the diagnosis of a general surgeon that does not require emergency surgery The patient must sign a consent form and cooperate during the study Has not been treated for hemorrhoids in the past month

Exclusion criteria:

Fourth-degree hemorrhoids Pregnancy Breastfeeding Diabetes Portal hypertension Various known coagulopathy Liver and kidney failure Inflammatory bowel diseases Perianal fissure Anal fistula Taking medication for hemorrhoids in the last 1 month History Hemorrhoid surgery in the last 6 months Thrombosed external hemorrhoid Strangulated internal hemorrhoid Anal abscess History of perianal surgery Mucosal prolapse Cancer and other malignancies

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are divided into two groups of 40 people randomly by simple block randomization method. All subjects are made aware of the content of the study and written informed consent was obtained from each patient. Coding and sealing of both suppositories by a non-researcher of the study is done by simple block randomization method and using Random Number Generation software. During that time the doctor, researcher and patients are not aware of the block numbers. Common anti-hemorrhoid suppositories are removed from the relevant company's packaging and placed in specially designed boxes for clinical trials, and the labels are removed. The Colo-Rectal Evaluation of Clinical Therapeutics Scale questionnaire (CORECTS) questionnaire completed by individuals. The Interventional group is taking a Traditional Rectal suppository and the control group Anti-hemorrhoid suppository. Both groups of people receive the Drugs in the form of sealed envelopes with a allocation concealment method, and it should be noted that the color and packaging of the both groups drugs are completely similar. The medication in all two groups is taking a rectal suppository for two weeks, twice a day. After the end of the consumption period, the patient's symptoms are evaluated by the questionnaire. The data are collected after 14 days, and then the codes of the drug packages and related questionnaires are opened.

Blinding (investigator's opinion)

Double blinded

Blinding description

The doctor and the patient are blinded in the study. The researcher provides the traditional rectal suppository and conventional anti-hemorrhoid suppository to the patient in sealed envelopes with a allocation concealment method, and the color and packaging of the both groups are completely similar.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Central Building of Medical Sciences, Zand Street.

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2023-12-08, 1402/09/17

Ethics committee reference number

IR.SUMS.REC.1402.430

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

Pain

Timepoint

Before intervention, 2 weeks after initiation of intervention

Method of measurement

Colo-Rectal Evaluation of Clinical Therapeutics Scale questionnaire (CORECTS)

2

Description

Itching

Timepoint

Before intervention, 2 weeks after initiation of intervention

Method of measurement

Colo-Rectal Evaluation of Clinical Therapeutics Scale questionnaire (CORECTS)

3

Description

Swelling

Timepoint

Before intervention, 2 weeks after initiation of intervention

Method of measurement

Colo-Rectal Evaluation of Clinical Therapeutics Scale questionnaire (CORECTS)

4

Description

Bleeding

Timepoint

Before intervention, 2 weeks after initiation of intervention

Method of measurement

Colo-Rectal Evaluation of Clinical Therapeutics Scale questionnaire (CORECTS)

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group: 28 rectal suppositories containing Commiphora mukul (Hook. Ex Stocks) Engl. and Allium porrum L. made by the researcher, BID for two weeks

Category

Treatment - Drugs

2

Description

The control group: 28 conventional anti hemorrhoid suppositories containing hydrocortisone acetate, lidocaine, aluminum sub acetate and zinc oxide, BID for two weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rahnemoun Hospital

Full name of responsible person

Abdolali Mohagheghzadeh

Street address

Farokhi Street, Shahid beheshti Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
Shiraz 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
Faculty of pharmacy
Full name of responsible person
Motahare Nayebzadeh
Position
PhD student, traditional pharmacy
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Person responsible for updating data

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PhD student, traditional pharmacy
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Only a part of data like primary outcome can be shared.
When the data will become available and for how long
The access period starts 1 year after the publication time of results
To whom data/document is available

This data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The data will be made available to researchers for further studies or more advanced analysis.

From where data/document is obtainable

Researchers can send an email regarding the request for the data of our study to Dr. Abdolali Mohagheghzadeh.

Email: mohaghegh@sums.ac.ir

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

The researchers can request for this study's data through an e-mail one year after the publication data of this study in one of the pee-reviewed journals.

Comments