

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of a natural cream on hemorrhoids in comparison with conventional anti-hemorrhoid ointment: A double-blind controlled trial

Protocol summary

Study aim

Determination of herbal anti hemorrhoid cream on hemorrhoid and comparing with a conventional ointment

Design

The study is a phase-3 controlled trial. There are two groups: Intervention and control. The sample size is 80 patients. The randomization method is a block design.

Settings and conduct

The study is performed in Emam Reza clinic, Shiraz University of Medical Sciences. On admission, after filling out the consent form, the patients will be visited by a gastroenterologist. Thereafter, proctoscopy will be done for each patient to detect any probable risky process and determine the degree of hemorrhoid. Then, the demographic form and diagnostic hemorrhoid checklist will be filled out for all patients. The drug and control, using for 14 days, are the same in the shape of the tube, package, and color of containing material. The study is double-blind, so the physician and patient remain blinded. After hand-washing, the tube content is used in the anal region using a special applicator one gram twice daily. In the 2nd visit, the patient will be asked to stop medication use for 28 days. In this period, the conventional anti hemorrhoid ointment will be rendered to all patients to use only when needed. The number of uses should be recorded by the patients. After 28 days the patients will come to the clinic for the final evaluation and filling out the checklist.

Participants/Inclusion and exclusion criteria

Inclusion: 1- Age 18 y/o and more 2- Hemorrhoid grade: 1 or 2 Non-inclusion: 3- Malignancy 4- Hypertension 5- Hepatic or renal failure 6- Diabetes mellitus

Intervention groups

Intervention group: Herbal cream, 1 gram, locally on the anal region, twice daily, for 14 days. Control group: Conventional anti hemorrhoid ointment, 1 gram, locally on the anal region, twice daily, for 14 days.

Main outcome variables

Hemorrhoid manifestations

General information

Reason for update

We need to update the recruitment start and finish dates

Acronym

IRCT registration information

IRCT registration number: **IRCT20141011019489N3**

Registration date: **2020-04-20, 1399/02/01**

Registration timing: **registered_while_recruiting**

Last update: **2024-09-26, 1403/07/05**

Update count: **1**

Registration date

2020-04-20, 1399/02/01

Registrant information

Name

Meysam Shirzad

Name of organization / entity

School of traditional medicine, Tehran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 4535

Email address

shirzad@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-22, 1397/06/31

Expected recruitment end date

2021-03-05, 1399/12/15

Actual recruitment start date

2020-04-01, 1399/01/13

Actual recruitment end date

2021-07-01, 1400/04/10

Trial completion date

Scientific title

Effect of a natural cream on hemorrhoids in comparison with conventional anti-hemorrhoid ointment: A double-blind controlled trial

Public title

Effect of a natural cream on hemorrhoids in comparison with the conventional ointment

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age: 18 and more Hemorrhoid Grade 1,2

Exclusion criteria:

Any types of malignancy Hypertension Hepatic or renal failure Diabetes mellitus

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **80**

Actual sample size reached: **49**

Randomization (investigator's opinion)

Randomized

Randomization description

We use two variables to remove the effect of confounding factors: age and weight. In this method, the effect of the abovementioned two variables is controlled via analysis of variance. So, the effect of the independent variable (drug) on the dependent variable will be determined. To control age and weight we use randomized block design, i.e. quadratic blocks for weight and binary blocks for age. According to that, the samples will be allocated into A and B groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The main researcher does not have any contact with the participants. The gastroenterologist only visits the participants and fills out the checklists. So, he will be kept unaware of the allocation into A or B groups. Moreover, the participants and the pharmacy technician who renders the ointments do not recognize the tubes (A or B) belonging to which group (drug or control). All tubes are the same form.

Placebo

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

6th Floor, Central building of Shiraz University of Medical Sciences Zand St., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2019-03-09, 1397/12/18

Ethics committee reference number

IR.SUMS.MED.REC.1398.034

Health conditions studied**1****Description of health condition studied**

Hemorrhoid

ICD-10 code

K64.0

ICD-10 code description

First degree hemorrhoids

2**Description of health condition studied**

Hemorrhoid

ICD-10 code

K64.1

ICD-10 code description

Second degree hemorrhoids

Primary outcomes**1****Description**

Manifestations of hemorrhoid

Timepoint

The onset of the intervention, 2 weeks later, 6 weeks later

Method of measurement

A checklist for hemorrhoid manifestations including 1- Anal pain (VAS zero to 10) 2- Difficulty in defecation (VAS zero to 10) 3- Bleeding severity (4-point Likert) 4- Anal pruritus (4-point Likert) 5- Anal burning (4-point Likert) 6- Subjective general improvement (percent)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Herbal cream containing the extract of oleaster, wild leek and camomile, and the essence of common myrtle. Route of administration and dose: Locally one gram on the anal region by a special applicator twice daily for 14 days. Manufacturer: Barij Essence Pharmaceutical Company

Category

Treatment - Drugs

2

Description

Control group: Anti-hemorrhoid ointment (containing lidocaine 5 grams+Hydrocortisone Acetate 0.275 grams+ Aluminium sub-acetate 3.5 grams+ Zinc oxide 18 grams%). Route of administration: Locally on the anal region by a special applicator twice daily for 14 days. Manufacturer: Aburaihan Pharmaceutical Company/Barij Essence Pharmaceutical Company. An edible green color is used for the placebo to change the color similar to the drug.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza clinic, Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Ebrahim Zohalinezhad

Street address

Namazi Sq.

City

Shiraz

Province

Fars

Postal code

7134871473

Phone

+98 71 3647 4673

Email

zohalinm@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mehrzad Lotfi

Street address

Zand St.

City

Shiraz

Province

Fars

Postal code

۷۱۳۳۶ - ۷۱۳۴۸

Phone

+98 71 3230 5410

Email

info@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Barij essence pharmaceutical company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Ebrahim Zohalinezhad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Zand St.

City

Shiraz

Province

Fars

Postal code

7134845794

Phone

+98 71 3208 4241

Email

zohalinm@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Meysam Shirzad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

No. 25 Sarparast Ave., Taleqani St.

City

Tehran

Province

Tehran

Postal code

1416663361

Phone

+98 21 8899 3656

Email

shirzad@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Ebrahim Zohalinezhad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Zand St.

City

Shiraz

Province

Fars

Postal code

7134845794

Phone

+98 71 3208 4241

Email

zohalinm@sums.ac.ir

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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The publication of data is restricted on demographic information and values obtained from the diagnostic checklist for hemorrhoids. This data will be published unrecognizably in the form of scientific articles in authentic journals.

When the data will become available and for how long

From March 2021 to March 2022

To whom data/document is available

All audiences

Under which criteria data/document could be used

The data can be used for similar researches under the prohibition of plagiarism

From where data/document is obtainable

The data is available online for all audiences

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

There is no process for obtaining information

Comments