Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effects of Terminalia Chebula Retz capsule (A product derived from Iranian traditional medicine) with placebo on the level of bleeding, pain and shirinking of the hemorrhoid pile mass: a randomized double-blind placebo-controlled trial

Protocol summary

Summary

The study purpose is assessment of the effects of terminalia chebula on hemorrhoid treatment in the patients with hemorrhoids refered to the Modarres hospital. This study is a randomized (based on randomized numbers table) double-blind placebo-controlled trial. Sample size is 40 patients in each group. Study duration is 4 weeks. In this study after taking a complete history, examination and rectosigmoidoscopy, the experimental group will receive one terminalia chebula capsule and the control group will receive one placebo capsule every 6 hours, on an empty stomach for four weeks. If the patients don't get any response from the treatment (capsules), they can use 30 to 60 cc lactulose syrup to improve constipation and one antihemorrhoids suppository to decrease pain in each day. Inclusion criteria include 18 to 65 year-old women and men who have grade I and II hemorrhoids. Exclusion criteria include every severe disease; presence of cancer in every part of the body; every disease in anorectal except hemorrhoids; pregnant and lactating women; patients with history of using anticoagulant, antiplatelet drugs, steroids drugs, drugs with flavonoids (less than a month ago) and pain killers (less than a week ago). Primary outcomes: pain, hemorrhoids bleeding and constipation are measured respectively based on VAS, number of days and ROM III criteria before and after the intervention, at the end of every week, for four weeks. Size of mass, as primary outcome in hemorrhoids, is measured before the intervention and at the end of the intervention by rectosigmoidoscopy. Secondary outcomes: headache, vertigo, diarrhea, constipation and dry skin are measured based on questionnaire before and after the intervention, at the end of every week, for four weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101830372N1**
Registration date: **2017-04-15, 1396/01/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-04-15, 1396/01/26

Registrant information

Name

Pouran Andarkhor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2286 2996

Email address

pouran.andarkhor@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of Terminalia Chebula Retz capsule (A product derived from Iranian traditional medicine) with placebo on the level of bleeding, pain and shirinking of the hemorrhoid pile mass: a randomized double-blind placebo-controlled trial

Public title

Effects of Terminalia Chebula on hemorrhoids

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria include 18 to 65 year-old women and men who have grade I and II hemorrhoids. Exclusion criteria include every severe disease; presence of cancer in every part of the body; every disease in anorectal except hemorrhoids; pregnant and lactating women; patients with history of using anticoagulant, antiplatelet drugs, steroids drugs, drugs with flavonoids (less than a month ago) and pain killers (less than a week ago).

Age

From **78 years** old to **31 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization of this study is based on random numbers table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

The Office of Management Research, Shahid Beheshti University of Medical Sciences, next to Taleghani Hospital, Evin, Shahid Chamran Highway

City

Tehran

Postal code

1985717443

Approval date

2016-10-02, 1395/07/11

Ethics committee reference number

IR.SBMU.RETECH.REC.1395.424

Health conditions studied

1

Description of health condition studied

hemorrhoids

ICD-10 code

184.2

ICD-10 code description

internal hemorrhoids without complications

Primary outcomes

1

Description

bleeding of hemorrhoids

Timepoint

Before and after the intervention, at the end of every week, for four weeks

Method of measurement

The number of days (questionnaire)

2

Description

Pain

Timepoint

Before and after the intervention, at the end of every week, for four weeks

Method of measurement

Visual Analog Scale (VAS) (questionnaire)

3

Description

The size of pilel mass

Timepoint

Before the intervention, and at the end of the intervention

Method of measurement

Rectosigmoidoscopy

4

Description

Constipation

Timepoint

Before and after the intervention, at the end of every week, for four weeks

Method of measurement

ROM III criteria (questionnaire)

5

Description
Exercise
Timepoint
Before and after the intervention, at the end of every week, for four weeks
Method of measurement
At least half an hour daily for 4 days a week (questionnaire)

Secondary outcomes

1

Description
Headache
Timepoint
Before and after the intervention, at the end of every week, for four weeks
Method of measurement
Visual Analog Scale (VAS) (questionnaire)

2

Description
Vertigo
Timepoint
Before and after the intervention, at the end of every week, for four weeks
Method of measurement
Grading of vertigo severity (questionnaire)

3

Description
Diarrhea
Timepoint
Before and after the intervention, at the end of every week, for four weeks
Method of measurement
Mild: <3 loose stools per day, Moderate: 3 to 10 per day, Severe: >10 per day (questionnaire)

4

Description
dry skin
Timepoint
Before and after the intervention, at the end of every week, for four weeks
Method of measurement
skin dry grading scale (questionnaire)

5

Description
constipation
Timepoint
Before and after the intervention, at the end of every week, for four weeks
Method of measurement
ROM III criteria (questionnaire)

Intervention groups

1

Description
Intervention group: The intervention group receive one terminalia chebula capsule with empty stomach every 6 hours for four weeks. If the patients did not get any positive response from the capsules, they can use 30 to 60 cc lactulose syrup because constipation is disappeared and one antihemorrhoids suppository daily because pain is disappeared.
Category
Treatment - Drugs

2

Description
Control group: The control group receive one placebo capsule with empty stomach every 6 hours for four weeks. If the patients did not get any positive response from the capsules, they can use 30 to 60 cc lactulose syrup because constipation is disappeared and one antihemorrhoids suppository daily because pain is disappeared.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Modarres Hospital
Full name of responsible person
Pouran Andarkhor
Street address
Modarres Hospital, Saadat Abad Boulevard and Yadegar Highway intersection, The end of Saadat Abad Boulevard
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Mahmood Mosadegh
Street address
Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Evin, Shahid Chamran Highway
City
Tehran

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, Shahid Beheshti 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
School of Traditional Medicine, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Pouran Andarkhor
Position
PhD candidate
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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