

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

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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
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 PhD candidate
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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