

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Assessing the effect of combined of terminalia chebula, rhubarb, aloe vera and lees seeds on the severity and accelerate the treatment of hemorrhoids

Protocol summary

Study aim

Effect of combined of terminalia chebula, rhubarb, aloe vera and lees seeds on the severity and accelerate the treatment of hemorrhoids

Design

80 participants (no=40 per group) are randomly assigned to intervention and placebo group using random digit table

Settings and conduct

This double blinded study will be performed in private clinic. At base line and after 8 weeks of intervention with supplement/placebo, hemorrhoid severity will be assessed using hemorrhoids severity score (HSS) questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age above 18 years, Having hemorrhoid according to internist diagnosis, Willing to participate in the study Exclusion criteria: Pregnancy, Lactation, Having any type of cancer, Having known renal disease

Intervention groups

Patients will receive 500 mg Ruhemorrin (Ghaem Daro company) capsule or placebo two times daily for 8 weeks. Each capsule contains terminalia chebula, rhubarb, aloe vera and lees seeds or maltodextrine in placebo group.

Main outcome variables

hemorrhoid severity using hemorrhoids severity score (HSS) questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140804018677N17**

Registration date: **2022-04-25, 1401/02/05**

Registration timing: **prospective**

Last update: **2022-04-25, 1401/02/05**

Update count: **0**

Registration date

2022-04-25, 1401/02/05

Registrant information

Name

soodeh razeghi Jahromi

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-05, 1401/02/15

Expected recruitment end date

2022-10-07, 1401/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of combined of terminalia chebula, rhubarb, aloe vera and lees seeds on the severity and accelerate the treatment of hemorrhoids

Public title

Effect of combined of Terminalia chebula, rhubarb, aloe vera and vegetable seeds on the severity and accelerate the treatment of hemorrhoids		Assignment Parallel	
Purpose Treatment		Other design features	
Inclusion/Exclusion criteria Inclusion criteria: Age above 18 years Having hemorrhoid according to internist diagnosis Willing to participate in the study Exclusion criteria: Pregnancy Lactation Having any type of cancer Having known renal disease		Secondary Ids empty	
Age From 18 years old		Ethics committees 1 Ethics committee Name of ethics committee Ethics committee of Shahid Beheshti medical university Street address No. 7, West Arghavan St., Farahzadi Blv., Qods Town City Tehran Province Tehran Postal code 1981619573 Approval date 2022-02-27, 1400/12/08 Ethics committee reference number IR.SBMU.RETECH.REC.1400.1134	
Gender Both		Health conditions studied 1 Description of health condition studied Hemorrhoid ICD-10 code K64.9 ICD-10 code description Unspecified hemorrhoids	
Phase 3		Primary outcomes 1 Description Hemorrhoid severity Timepoint Baseline and at the end of the study Method of measurement hemorrhoids severity score (HSS)	
Groups that have been masked • Participant • Care provider • Investigator • Outcome assessor • Data analyser		Secondary outcomes empty	
Sample size Target sample size: 80		Intervention groups 1 Description Intervention group: 500 mg Ruhemorrin (Ghaem Daro) capsule two times daily for 8 weeks	
Randomization (investigator's opinion) Randomized			
Randomization description Participants will have equal chance to be assigned to studied groups. We will use random digits table to make random sequence. After determining the first number, we will continue downward and allocate even numbers to cases and odd numbers to placebo. As in small sample sizes, it would be probable that one group be completed earlier, if one group completed earlier, we will allocate the other assigned numbers to other group. A person out of study group will put her figure on one digit of the table with closed eyes and according to assumed agreement will go downward through the table and write the numbers down until completing the sample size in each group. Code "A" will allocated to even numbers and considered as "intervention group" and code "B" will allocated to odd numbers and considered as "placebo group". At the end we will have the sequence of 80 specific numbers and A&B codes. A person out of study team will put the numbers in sealed packets till the time of sampling			
Blinding (investigator's opinion) Double blinded			
Blinding description It is a double blind study. A third person out of study team have the sequence of codes that provide the team with sealed pockets containing allocation code (supplement and placebo) at the time of sampling. The following groups of people: participants, research team including principle investigator, data collectors, and outcome assessors will be blind			
Placebo Used			

Category

Treatment - Other

2**Description**

Control group: Placebo contain maltodextrine, (500 mg),
Ghaem darou company, two times daily for 8 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

private clinic

Full name of responsible person

Soodeh Razeghi Jahromi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soodeh Razghei Jahromi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data would be available to public

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

To all

Under which criteria data/document could be used

No other criteria

From where data/document is obtainable

Email to soodehrazeghi@gmail.com

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

Sending email to me

Comments