Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Terminalia chebula Therapeutic effects in Patients With Symptomatic Hemorrhoids in reducing hemorrhage

Protocol summary

Study aim
Evaluation of the effect of Terminalia chebula on the severity of hemorrhage

Design
A randomized, controlled, single-blind, placebo-controlled clinical trial

Settings and conduct
This study is a single-blind randomized clinical trial (which only patients do not know the type of drug) in 42 hemorrhoid patients referred to Sina Hospital.

Participants/Inclusion and exclusion criteria
Inclusion criteria are: 1. Internal hemorrhoids 2. Patient hemorrhoids grade one, two and three 3. Having informed written consent to participate in the study Exclusion criteria: Internal grade IV hemorrhoids 2. External hemorrhoids 3. Systemic disease 4. Anal fissure 5. Perineal abscess 6. Perianal fistula 7. Cirrhosis 8. Inflammatory bowel disease (IBD) 9.Those who have not received the full course of treatment or are experiencing medical complications.

Intervention groups
In the intervention group standard treatment (lifestyle modification including high fiber diet, intake of more liquids, forcing during excretion, personal hygiene to reduce itching of the anal area) is given with the ointment containing the active ingredient of Terminalia chubula. The control group received standard treatment (lifestyle modification including high fiber diet, intake of more liquids, forcing during excretion, personal hygiene to reduce anal itching) with ointment containing fixed substance .

Main outcome variables
Severity of bleeding; Pain; Itching; Defecation discomfort

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190915044780N1**
Registration date: **2020-05-09, 1399/02/20**
Registration timing: **prospective**

Last update: **2020-05-09, 1399/02/20**
Update count: **0**

Registration date
2020-05-09, 1399/02/20

Registrant information

Name
Abolfazl Bariklou

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 25 3285 2259

Email address
ab43477479@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

Expected recruitment end date
2020-08-21, 1399/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Terminalia chebula Therapeutic effects in Patients With Symptomatic Hemorrhoids in reducing hemorrhage

Public title
Terminalia chebula Therapeutic effects in Patients With

Symptomatic Hemorrhoids

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Internal hemorrhoids Patient hemorrhoids grade one, two and three Having informed written consent to participate in the study

Exclusion criteria:

Internal Grade Four Hemorrhoids external hemorrhoid Systemic disease anal fissure anal abscess anal fistula cirrhosis Inflammatory bowel disease (IBD) Those who have not received the full course of treatment or are experiencing medical complications.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization In this method, we use simple randomization models, such as computer randomization methods, and place each patient in the intervention or control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

In addition to routine treatment, patients are given ointments that patients do not know about the type of ointment (which may contain the active ingredient of Terminalia chubula or just placebo).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Research Ethics Committee School of Medicine- Tehran University of Medical Sciences

Street address

No. 23, 16 Azar Ave., Keshavarz Blvd.,Tehran

City

Tehran

Province

Tehran

Postal code

1417863181

Approval date

2019-09-04, 1398/06/13

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.484

Health conditions studied

1

Description of health condition studied

Hemorrhoids

ICD-10 code

K64

ICD-10 code description

Hemorrhoids and perianal venous thrombosis

Primary outcomes

1

Description

severity of hemorrhage

Timepoint

At the beginning of treatment and then weekly for 3 weeks

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group standard treatment (lifestyle modification including high fiber diet, intake of more liquids, forcing during excretion, personal hygiene to reduce itching of the anal area) is given with the ointment containing the active ingredient of Terminalia chubula. The way to use the ointment is to put a teaspoon of ointment on your finger and apply it to the area of your anus. Do this twice a day for three weeks. All the steps of using the ointment will be fully explained to the patients. In this study we use a dose of 5% ointment of Terminalia chubula. The only difference in this study is to evaluate the efficacy of the plant only The pharmacokinetics and drug release rate will be evaluated in future studies.

Category

Treatment - Drugs

2

Description

Control group: The control group received standard

treatment (lifestyle modification including high fiber diet, intake of more liquids, forcing during excretion, personal hygiene to reduce anal itching) with ointment containing fixed substance.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Hossein Zabihi Mahmoudabadi

Street address

Sina Hospital, Hassan Abad Square, Imam Khomeini Avenue

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6675 7001

Email

hzabihim@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

Street address

Sina Hospital, Hassan Abad Square, Imam Khomeini Avenue

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Phone

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Hossein Zabihi Mahmoudabadi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Sina Hospital, Hassan Abad Square, Imam Khomeini

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

hossein zabihi mahmoudabadi

Position

Associate professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Abolfazl Bariklou

Position
student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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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
Only part of the data, such as information about the main outcome, is shared.

When the data will become available and for how long
The access period begins 6 months after the results are published.

To whom data/document is available
It will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used
The data can be used for further documentation and study. In the case of data analysis, the Person responsible for updating data is responsible for delivering the data depending on the type of decision.

From where data/document is obtainable
To access the data, the persons can send an email message to the project manager. dr zabihi email: hzabihim@tums.ac.ir

What processes are involved for a request to access data/document
Depending on the type of application, the applicant arrives up to 2 months after the application has been submitted.

Comments