Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The efficacy of M.G Ointment containing essential oil of Myrtus and comparison of anti-hemorrhoid Ointment in reducing the severity of hemorrhoids and its complications

Protocol summary

Study aim
Comparison of M.G ointment with antihemorrhoid ointment in reducing the severity of hemorrhoids and their complications

Design
This study will be conducted as a randomized clinical trial with a parallel design, double-blind, drug-controlled phase 3 on patients with hemorrhoids grade I and II. Patient sampling will be convenient and after admission, patients will be randomly assigned to three treatment groups of 36 in a block design. In this way, blinding will be three-way. The drug intake in all three groups will be twice a day for two weeks. The study will be conducted as an ITT. Treatment adherence will be assessed by telephone calls to patients.

Settings and conduct
The study on patients in Kashan will be conducted in a triple-blind manner, with the drugs being filled in the same packaging and tube, and the only difference between the drugs in the three treatment groups being the numerical code created during the randomization phase.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with grade 1 or 2 hemorrhoids Exclusion criteria: Thrombosed external hemorrhoids; strangulated internal hemorrhoids; anal fistula; anal fissure; anal abscess; pregnancy; portal hypertension; grade 3 and 4 hemorrhoids; renal failure; malignant diseases

Intervention groups
Intervention group 1: M.G ointment containing 5% Myrtus essential oil manufactured by Barij Essence Pharmaceutical Company Intervention group 2: M.G ointment containing 10% Myrtus essential oil manufactured by Barij Essence Pharmaceutical Company Control group: Antihemorrhoid ointment manufactured by Caspian Pharmaceutical Company

Main outcome variables
Hemorrhoid severity, bleeding severity, pain during bowel movements

General information

Reason for update

Acronym
MG

IRCT registration information
IRCT registration number: **IRCT20220512054829N6**
Registration date: **2025-08-12, 1404/05/21**
Registration timing: **registered_while_recruiting**

Last update: **2025-08-12, 1404/05/21**
Update count: **0**

Registration date
2025-08-12, 1404/05/21

Registrant information

Name
Hossein Akbari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 5554 0111

Email address
akbari1350_h@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-06, 1404/05/15

Expected recruitment end date
2026-03-06, 1404/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of M.G Ointment containing essential oil of Myrtus and comparison of anti-hemorrhoid Ointment in reducing the severity of hemorrhoids and its complications

Public title

The effect of M.G ointment on reducing the severity of hemorrhoids

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with grade 1 or 2 hemorrhoids

Exclusion criteria:

Thrombosed external hemorrhoids Strangulated internal hemorrhoids Fistula, fissure and abscess of anal Pregnancy Portal hypertension Renal failure Malignant diseases

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is performed using the permuted block randomization method, in which all 6 blocks containing three codes A, B, and C are prepared (15 blocks), then random blocks are selected by permutation using a random number table. These blocks form a sequence of codes A, B, and C equal to the sample size, with each code randomly assigned to one of the groups. All randomization steps will be performed in the Clinical Trial Randomization Tool software at https://ctrandomization.cancer.gov.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The medicines are manufactured and prepared in the same packaging, appearance, and size at Barij Essans Pharmaceutical Company. They are then coded based on codes previously prepared using a random number table.

Placebo

Not used

Assignment

Parallel

Other design features

The study will be conducted in three treatment groups in parallel.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Faculty of Medicine & Faculty of Dentistry- Kashan University of Medi

Street address

Pezeshk Blvd; Ghotb Ravandi Blvd

City

Kashan

Province

Isfehan

Postal code

8715973449

Approval date

2025-05-11, 1404/02/21

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1404.031

Health conditions studied

1

Description of health condition studied

Hemorrhoid

ICD-10 code

K64.1

ICD-10 code description

K64.0

Primary outcomes

1

Description

Hemorrhoid severity

Timepoint

Study start, after two weeks of treatment

Method of measurement

Clinical assessment of disease symptoms based on VAS criteria by the surgeon

2

Description

Severity of Pain

Timepoint

Study start, after two weeks of treatment

Method of measurement

Based on the NRS-11 criterion

3

Description
Severity of Bleeding
Timepoint
Study start, after two weeks of treatment
Method of measurement
Clinical assessment and patient report

4

Description
Severe pain during bowel movements
Timepoint
Study start, after two weeks of treatment
Method of measurement
Based on the NRS-11 criterion

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: recipients of MG ointment with a high percentage of essential oil (10% essential oil)
Category
Treatment - Drugs

2

Description
Intervention group: recipients of MG ointment with a high percentage of essential oil (5% essential oil)
Category
Treatment - Drugs

3

Description
Control group: Recipients of anti hemorrhoid ointment
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان شهید بهشتی، کلینیک تخصصی جراحی
Full name of responsible person
حسین صادقی حسن آباد
Street address
Pezeshk Blvd; Ghotb Ravandi Blvd
City
Kashan
Province
Isfehan
Postal code
8715973449
Phone
+98 31 5558 9396
Email
hos.sad.642@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
Street address
Pezeshk Blvd. ; Ghotb Ravandi Blvd
City
Kashan
Province
Isfehan
Postal code
8715973449
Phone
+98 31 5510 3529
Email
hamiidi@yahoo.com
Grant name
404014
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
Kashan University of Medical Sciences
Full name of responsible person
Hossein Akbari
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Biostatistics
Street address
Pezeshk Blvd. ; Ghotb Ravandi Blvd

City
Kashan
Province
Isfehan
Postal code
8715973449
Phone
+98 31 5558 9396
Email
akbari1350_h@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hossein Akbari
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Biostatistics
Street address
Pezeshk Blvd. ; Ghotb Ravandi Blvd
City
Kashan
Province
Isfehan
Postal code
8715973449
Phone
+98 31 5558 9396
Email
akbari1350_h@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hossein Akbari
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Biostatistics
Street address
Pezeshk Blvd. ; Ghotb Ravandi Blvd
City
Kashan
Province
Isfehan
Postal code
8715973449
Phone
+98 31 5558 9396
Email
akbari1350_h@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Given that the sponsor of this study is a private company, publication of the data file should take place after the publication of the article.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is 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
Given that patient information must remain confidential, any request to receive patient information will be made with the approval of the university's ethics committee.
When the data will become available and for how long
At least one year after the design is completed and the article is published
To whom data/document is available
All researchers will have access to the data. Only the name and disease details will be kept confidential
Under which criteria data/document could be used
Researchers interested in using the data from this study will have access with approval from the university's ethics committee.
From where data/document is obtainable
Telephone call to the university's vice president for research or the project manager
What processes are involved for a request to access data/document
Submitting the request to the Vice President for Research of the University Referring the request to the Project Manager Letter from the Project Manager to the University Ethics Committee Approval by the University Ethics Committee Sending the required data and information to the applicant
Comments