Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Investigating the efficacy of herbal ointment (Chamomile and Myrtus) compared to anti-hemorrhoid ointment in the treatment of patients with hemorrhoids in a randomized clinical trial

Protocol summary

Study aim
This study aims to investigate the efficacy and safety of a rectal product containing Myrtle's and Chamomile in hemorrhoids compared to anti-hemorrhoid ointment

Design
Clinical trial with a parallel control group, with a sample size of 90 patients, single blind, randomized by block randomization method

Settings and conduct
Patients referring to the outpatient clinic of gastroenterology and general surgery and colonoscopy department of the Imam Khomeini Hospital Complex, who are diagnosed with hemorrhoids, will be evaluated. An announcement poster about the study will be provided in pharmacies of the faculty of pharmacy and social media to accelerate recruitment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 20 to 65 years; Hemorrhoid grade 1-2 based on the BPRST definition (bleeding, prolapse, reduction, skin tags, thrombosis) Non-inclusion criteria: several underlying diseases, using the research medication or medications with the same active ingredient

Intervention groups
In the intervention group, Rectus® ointment (Iran Darouk) is used rectally, one applicator (1gram) twice a day for two weeks. Patients in control group receive anti-hemorrhoid ointment (Aburihan) rectally similarly. Both groups receive proper laxative and recommendations on lifestyle modification orally and written.

Main outcome variables
Severity of hemorrhoid symptoms before and two weeks after the start of the intervention

General information

Reason for update
Due to the completion of the study, the dates of enrollment is determined and updated in the text.

Acronym

IRCT registration information
IRCT registration number: **IRCT20120125008819N3**
Registration date: **2022-12-12, 1401/09/21**
Registration timing: **prospective**

Last update: **2025-02-05, 1403/11/17**
Update count: **1**

Registration date
2022-12-12, 1401/09/21

Registrant information

Name
Mona Kargar

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8881 4157

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mkargar@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date
2023-08-23, 1402/06/01

Actual recruitment start date
2022-12-22, 1401/10/01

Actual recruitment end date
2023-10-03, 1402/07/11

Trial completion date
2023-10-17, 1402/07/25

Scientific title
Investigating the efficacy of herbal ointment (Chamomile and Myrtus) compared to anti-hemorrhoid ointment in the treatment of patients with hemorrhoids in a randomized clinical trial

Public title
Comparison of the efficacy of Chamomile and Myrtus ointment in comparison with anti-hemorrhoid ointment

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 20 to 65 years Hemorrhoid grade 1-2 based on the BPRST definition

Exclusion criteria:
Hemorrhoid requiring surgery External thrombosed and strangulated hemorrhoid Anal fistula Anal fisher Anal abscess Portal hypertension Pregnancy Breastfeeding History of inflammatory bowel diseases History of gastrointestinal malignancy Severe and acute cardiovascular disease Severe and acute liver disease Renal failure Asthma Using oral corticosteroids Food or inhalation allergy needs medication therapy Use of the current research medications Rectal use of medications with the same active ingredient as the research medications

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **100**
Actual sample size reached: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be allocated to the intervention and control groups using the block randomization method (block of 4). Randomization will be done centrally and before the initiation of the study by someone who is not directly involved in the recruitment of participants. Those who enroll patients in the study will not know the order of allocations. A senior researcher and clinical trial supervisor prepare a patient allocation plan based on the randomization list. Group codes of new patients will be handed over in separate sealed envelopes to the senior field researcher. So, the allocation of new patients to the groups will be hidden and will not be predictable

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the products' characteristics, it is impossible to blind the patient in this study, and the study is conducted as a single-blind study. The researcher who evaluate the outcomes will not be aware of the medication received by the patients. In other words, the assignment of patients to groups and handing the drugs to patients will be done by another researcher.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Imam Khomeini Hospital Complex, Tehran University of Medical Sciences

Street address
Imam Khomeini Hospital Complex, Bagherkhan St., Chamran highway

City
Tehran

Province
Tehran

Postal code
1419733141

Approval date
2022-10-18, 1401/07/26

Ethics committee reference number
IR.TUMS.IKHC.REC.1401.210

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 hemorrhoid signs/symptoms including bleeding, persistent pain, pain during defecation, anal itching, and tenesmus

Timepoint
Before, one week, andtwo weeks after the initiation of the study

Method of measurement
The presence and severity of each of the signs/symptoms (from 1 to 10) based on taking a history

2

Description
Severity of hemorrhoid symptoms considering their interferences with daily activity (Scores 0-3)
Timepoint
Before and two weeks after the initiation of the study
Method of measurement
History taking (0=no symptoms, 1=symptoms without any effects on daily activity, 2= symptoms that affects daily activity, 3= Severe interference with daily activity)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Rectal ointment containing Myrtle and Chamomile: In the intervention group, Rectus® ointment (produced by Iran Darouk Company) is used rectally, one applicator (containing one gram of the ointment) twice a day for two weeks. Every 30 grams (one tube) of Rectus® Ointment contains 8.1 grams of standardized essential oil of Myrtus communis and 0.3 grams of dried Matricaria chamomilla extract.
Category
Treatment - Drugs

2

Description
Control group: Rectal ointment of anti-hemorrhoids: Patients assigned to the control group receive anti-hemorrhoid ointment (produced by Aburihan company) rectally, one applicator (containing one gram of the ointment) twice a day for two weeks. Anti-hemorrhoid ointment contains hydrocortisone acetate (2.75 mg/g), lidocaine (50 mg/g), aluminum subacetate (35 mg/g) and zinc oxide (180 mg/g).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
Foroogh Alborzi Avanaki
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Tehran University of medical Sciences, Ghods St junction with Keshavarz Blvd
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vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Iran Darouk Pharmaceutical-Cosmetic 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
Tehran University of Medical Sciences
Full name of responsible person
Mona Kargar
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available