

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Evaluation of the effect of ointment containing extract of Persian honeylocust(*GleditsiaCaspica*) on clinical symptoms and quality of life in patients with hemorrhoids: A randomized clinical trial

Protocol summary

Study aim

The main aim of this study was to determine the effect of ointment containing herbal extract on clinical symptoms and quality of life in patients with hemorrhoids. The specific objectives are: to determine the effect of herbal ointment on the pain and discomfort in the rectum, the severity and frequency of rectorrhagia, rectal itching, lactulose consumption and quality of life of patients, side effects and possible satisfaction.

Design

A randomized, blinded, and controlled clinical trial with a parallel group design of 60 patients with hemorrhoids.

Settings and conduct

Among the patients with hemorrhoids referred to the clinics of the educational center and the office, 60 eligible patients will be randomly and blindly divided into two groups receiving ointments containing plant extracts or placebo ointments. Participants, main researchers, data collectors and assessor will be kept blind. Patients will use one gram of herbal ointment or placebo with the applicator every 12 hours for 2 weeks.

Participants/Inclusion and exclusion criteria

Patients 18 to 65 years of age with hemorrhoids with bleeding or hemorrhoidal prolapse or pain or both or all together and no anorectal disease and thrombosis and gangrenous hemorrhoids

Intervention groups

Herbal or placebo ointment recipient

Main outcome variables

Primary outcome: pain and bleeding Secondary outcome: pruritus, quality of life, complications, and satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220122053783N1**

Registration date: **2022-02-20, 1400/12/01**

Registration timing: **prospective**

Last update: **2022-02-20, 1400/12/01**

Update count: **0**

Registration date

2022-02-20, 1400/12/01

Registrant information

Name

Arezoo Moini Jazani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3353 4776

Email address

a.moini@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-21, 1400/12/02

Expected recruitment end date

2022-10-24, 1401/08/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of ointment containing extract of Persian honeylocust(*GleditsiaCaspica*) on clinical symptoms and quality of life in patients with

hemorrhoids: A randomized clinical trial

Public title
Persian honeylocust ointment in hemorrhoids

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with grade 1-2 internal hemorrhoids Age 18-65 years Patients with bleeding or hemorrhoidal prolapse or pain or two or all together Have a signed informed consent form to participate in the study
Exclusion criteria:
 Anorectal diseases such as rectal prolapse, Fisher, fistula, perianal abscess Thrombosis and gangrenous hemorrhoids Uncontrolled cardiovascular disease Cirrhosis Inflammatory bowel disease (IBD) Pregnancy and lactation History of allergy to herbal medicines Use analgesics less than a week ago Use of anticoagulants less than a month ago Use of steroid less than a month ago Unwillingness to participate in the study

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly assigned to the intervention and control groups in a block method. The samples will be determined by random blocking method with 2 blocks and using the table of random numbers obtained from Random Allocation Software. Blocking and allocation sequencing for concealment will be done by the person not involved in the research (Allocation Concealment). The sample allocation ratio will be 1:1 (Allocation 1: 1) and will be placed in two groups receiving ointment containing herbal extract or placebo ointment (Assignment). Then, the ointments will be delivered to the participants based on the obtained blocks and in the order of allocation.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants, the main researchers of the study, the physician, the data collector, and the outcome assessor will be kept blind. The ointments are packed in the same shape tubes and numbered from one to 60 and finally are delivered to the participants in order.

Placebo

Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Ardabil University of Medical Sciences
Street address
 Daneshgah st, Ardabil Complex Univesity
City
 Ardabil
Province
 Ardabil
Postal code
 56189-85991
Approval date
 2021-11-29, 1400/09/08
Ethics committee reference number
 IR.ARUMS.REC.1400.279

Health conditions studied

1

Description of health condition studied
Hemorrhoid

ICD-10 code
K64.8

ICD-10 code description
Other hemorrhoids

Primary outcomes

1

Description
Pain according to CORECTS questionnaire

Timepoint
At the first (before starting the study), end of the first and the second week

Method of measurement
Colo-Rectal Evaluation of Clinical Therapeutics Scale (CORECTS) questionnaire

2

Description
Rectorrhagia according to CORECTS questionnaire

Timepoint
At the fist (before starting the study), end of the first and the second week

Method of measurement

Secondary outcomes

1

Description

Itching according to CORECTS questionnaire

Timepoint

At the fist (before starting the study), end of the first and the second week

Method of measurement

Colo-Rectal Evaluation of Clinical Therapeutics Scale (CORECTS) questionnaire

2

Description

Quality of Life

Timepoint

At the fist (before starting the study), end of the first and the second week

Method of measurement

The World Health Organization Quality of Life Instrument, Short Form (WHOQOL-BREF) questionnaire

3

Description

Possible side effects of treatment

Timepoint

At the fist (before starting the study), end of the first and the second week

Method of measurement

Researcher-made questionnaire

4

Description

Satisfaction of treatment

Timepoint

At the fist (before starting the study), end of the first and the second week

Method of measurement

Researcher-made questionnaire (according to Visual Analogue Scale)

Intervention groups

1

Description

Intervention group: they will receive an ointment containing hydroalcoholic extract of Persian honeylocust (Gleditsia Caspica) 1 gram/two times a day using an applicator for 2 weeks. Ointments were prepared in Shafa Pajohan Sabz Company, Tabriz, Iran.

Category

Treatment - Drugs

2

Description

Control group: Intervention group: they will receive an ointment containing eucerine 1 gram/two times a day using an applicator for 2 weeks. Ointments were prepared in Shafa Pajohan Sabz Company, Tabriz, Iran.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Fatemi Hospital

Full name of responsible person

Dr. Mirsalim Seyed Sadeghi

Street address

Sarein Station, Imam Khomeini St., not far from Shariati Square, Dr Fatemi Hospital

City

Ardabil

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2

Recruitment center

Name of recruitment center

Clinic of Dr. Seyed Sadeghi

Full name of responsible person

Mir Salim Seyed Sadeghi

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr.Farhad Pourfarzi

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Daneshgah st. Ardabil Complex Univesity

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info@arums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Shafa pajohan sabz Company, Tabriz, Iran

Proportion provided by this source

50

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

Ardabil University of Medical Sciences

Full name of responsible person

Arezo Moini Jazani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Sarein Station, Imam Khomeini St., not far from

Shariati Square, Dr. Fatemi Hospital

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Arezo Moini Jazani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Phone

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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