Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

Evalution 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

Evalution 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 ofArdabil 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

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

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
Province
Ardabil
Postal code
5614733775
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fatemi@arums.ac.ir

2

Recruitment center
Name of recruitment center
Clinic of Dr. Seyed Sadeghi
Full name of responsible person
Mir Salim Seyed Sadeghi
Street address
Sarcheshmeh Square, Toi Alley, Navid Doctors Building
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salim.seyedsadeghi95@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person

Dr.Farhad Pourfarzi

Street address
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
Arezoo Moini Jazani

Position
Assisstant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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Person responsible for scientific inquiries

Contact

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Ardabil University of Medical Sciences

Full name of responsible person
Mirsalim Seyed Sadeghi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
General Surgery

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

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Email
salim.seyedsadeghi95@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Ardabil University of Medical Sciences

Full name of responsible person
Arezoo Moini Jazani

Position
Assisstant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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dr.moeeni@yahoo.com

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