Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Elaeagnus angustifolia cream on hemorrhoid symptoms in pregnant women

Protocol summary

Study aim
Evaluation of the effect of Elaeagnus angustifolia cram on hemorrhoid symptoms in pregnant women

Design
Clinical trial with control group, parallel group, triple blind, randomized, phase3, on 100 pregnant women, use www.sealedenvelope.com for randomization.

Settings and conduct
This study will be conducted on 100 eligible pregnant women attending at Health Center No.1 in Mashhad. Participants will be randomly allocated to two group using a randomized block design. An independent pharmacist will be responsible for coding and the researcher, participants and statistician will remain blinded. Participants will be evaluated for symptoms at baseline,1 week and 2 weeks after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Able to read and write, Pregnancy women aged 18-45 years, Singleton pregnancy, Gestational age between14 and 34 weeks, Body mass index of less than 30, Willingness to participate in the study, Presence of grade 1 or 2 hemorrhoids; Exclusion criteria: Concurrent participation in another interventional study, History of hemorrhoid surgery in the last month, Presence of specific underlying diseases, obstetric complications, or other colorectal disorders, Allergy to Elaeagnus angustifolia, Use of anti-hemorrhoid drugs or systemic steroids during the two weeks before the study

Intervention groups
Intervention group: Participants will receive lifestyle modification education and will apply 3 gram of cream containing 5 pecent hydroalcoholic extract of Elaeagnus angustifolia fruit topically every 12 hours for 2 weeks. Placebo group: Participants will receive lifestyle modification education and will apply 3 gram of base cream (without the extract) topically every 12 hours for 2 weeks.

Main outcome variables
Severity of hemorrhoid symptoms including pain, itching, swelling, bleeding, discomfort and the negative impact of hemorrhoids on wellbeing.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260609069717N1**
Registration date: **2026-09-22, 1405/06/31**
Registration timing: **prospective**

Last update: **2026-09-22, 1405/06/31**
Update count: **0**

Registration date
2026-09-22, 1405/06/31

Registrant information

Name
Fatemeh Dehghan Tarzjani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3604 0695

Email address
dehghanif4032@mums.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-07, 1405/07/15

Expected recruitment end date
2027-05-05, 1406/02/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Elaeagnus angustifolia cream on hemorrhoid symptoms in pregnant women

Public title

The effect of Elaeagnus angustifolia cream on hemorrhoids during pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Able to read and write Pregnancy women aged 18-45 years Singleton pregnancy Gestational age between14 and 34 weeks Body mass index of less than 30 Willingness to participate in the study Presence of grade 1 or 2 hemorrhoids

Exclusion criteria:

Concurrent participation in another interventional study History of hemorrhoid surgery in the last month Presence of specific underlying diseases, obstetric complications, or other colorectal disorders Allergy to Elaeagnus angustifolia Use of anti-hemorrhoid drugs or systemic steroids during the two weeks before the study

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly allocated to two groups using a randomized block design. The blockrand package will be employed through the website www.sealedenvelope.com. In the specified function, the number of treatment groups will be set to 2 and the block size to 4. The generated allocation sequence will be random with ablock size of four, and participants will be assigned to the intervention and control groups based on this sequence.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is designed as a triple-blind randomized controlled trial. The researcher, participants, and statistician will be blinded to group allocation(intervention vs. control). An independent pharmacist(no involvement in sample allocation, intervention, or patient assessment) will be responsible for coding. Tubes containing the active cram and placebo will be labeled as A and B.The data provided to the statistician will be coded to ensure the group identity remains undisclosed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Shahid Dr. Kharazmi Educational Complex, University Campus, East Gate of Ferdowsi University of Mashhad, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2026-08-03, 1405/05/12

Ethics committee reference number

IR.MUMS.NURSE.REC.1405.060

Health conditions studied

1

Description of health condition studied

Hemorrhoids in pregnancy

ICD-10 code

O22.4

ICD-10 code description

Hemorrhoids in pregnancy

Primary outcomes

1

Description

Severity of hemorrhoid pain

Timepoint

Before the intervention, 1 week and 2 weeks after the start of the intervention

Method of measurement

Colo-Rectal Evaluation of Clinical Therapeutics Scale

2

Description
Severity of hemorrhoid swelling
Timepoint
Before the intervention, 1 week and 2 weeks after the start of the intervention
Method of measurement
Colo-Rectal Evaluation of Clinical Therapeutics Scale

3

Description
Severity of hemorrhoid bleeding
Timepoint
Before the intervention, 1 week and 2 weeks after the start of the intervention
Method of measurement
Colo-Rectal Evaluation of Clinical Therapeutics Scale

4

Description
Severity of hemorrhoid itching
Timepoint
Before the intervention, 1 week and 2 weeks after the start of the intervention
Method of measurement
Colo-Rectal Evaluation of Clinical Therapeutics Scale

5

Description
Severity of anal discomfort
Timepoint
Before the intervention, 1 week and 2 weeks after the start of the intervention
Method of measurement
Colo-Rectal Evaluation of Clinical Therapeutics Scale

6

Description
Negative impact score of hemorrhoids on well-being
Timepoint
Before the intervention, 1 week and 2 weeks after the start of the intervention
Method of measurement
Colo-Rectal Evaluation of Clinical Therapeutics Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Eligible pregnant women with hemorrhoid symptoms, confirmed as grade 1 or 2 by a physician at the health center, will receive lifestyle modification education and will apply 3 g of 5% oleaster extract cream (prepared at the Pharmacological Research Center for Medicinal Plants, Mashhad University of Medical Sciences) topically every 12 hours for 2 weeks.
Category
Treatment - Drugs

2

Description
Control group:Eligible pregnant women with hemorrhoid symptoms, confirmed as grade 1 or 2 by a physician at the health center, will receive lifestyle modification education and will apply 3 g of the base cream (without extract, prepared at the Pharmacological Research Center for Medicinal Plants, Mashhad University of Medical Sciences) topically every 12 hours for 2 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Najafi Comprehensive Health Center
Full name of responsible person
Fatemeh Dehghan
Street address
Hagh-Shenas 4, Pirouzi 18, Pirouzi Boulevard
City
Mashhad
Province
Razavi Khorasan
Postal code
9179793945
Phone
+98 51 3879 8999
Email
DehghaniF4032@mums.ac.ir

2

Recruitment center
Name of recruitment center
Shahid Saffari Comprehensive Health Center
Full name of responsible person
Fatemeh Dehghan
Street address
Hashemieh 33, Hashemieh Boulevard, next to the mosque
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Phone
+98 51 3884 8189
Email
DehghaniF4032@mums.ac.ir

3

Recruitment center

Name of recruitment center
Danesh Amooz Comprehensive Health Center

Full name of responsible person
Fatemeh Dehghan

Street address
Danesh Amooz Boulevard, adjacent to Farhang Square

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Province
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9188873655

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4

Recruitment center

Name of recruitment center
Emamat Comprehensive Health Center

Full name of responsible person
Fatemeh Dehghan

Street address
Esteghlal 5, Esteghlal Boulevard, Beyhaghi North, between Beyhaghi 27 and 29

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DehghaniF4032@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Mohsen Tafaghodi

Street address
Vice Chancellery for Research and Technology, Shahid Dr. Kharazmi Educational Complex, University Campus, East Gate of Ferdowsi University of Mashhad, Azadi Square

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TafaghodiM@mums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Fatemeh Dehghan

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Shahid Dr. Kharazmi Educational Complex, University Campus, East Gate of Ferdowsi University of Mashhad, Azadi Square

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DehghaniF4032@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mahboobeh Firoozi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery
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Person responsible for updating data

Contact
Name of organization / entity
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Position
Student
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Midwifery
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Shahid Dr. Kharazmi Educational Complex, University Campus, East Gate of Ferdowsi University of Mashhad, Azadi Square
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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