Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effects of massage with Elaeagnus angustifolia oil and massage with lavender oil on anxiety and labor pain in pregnant women

Protocol summary

Study aim
Determining the effect of massage with oleaster oil and massage with lavender oil on anxiety and labor pain in pregnant women

Design
A phase 3, randomized, non-blinded, parallel-group, controlled clinical trial on 80 patients. RAND function of Microsoft Excel

Settings and conduct
A randomized clinical trial will be conducted on 80 mothers who present with labor pain to Allameh Bohlool Hospital in Gonabad. Participants will be selected using convenience sampling and randomly assigned using block randomization with blocks of four into two groups of 40: massage therapy with oleaster oil and massage therapy with lavender oil. Pain and anxiety intensity will be measured and recorded for both groups before and after the intervention using the Visual Analog Scale

Participants/Inclusion and exclusion criteria
Healthy, alive, single fetus with no anomalies First to third delivery fetal weight 2500 to 4000 grams Fetal lie is longitudinal and the presenting part is cephalic Gestational age 37 and 41 weeks Body mass index at delivery 18.5 and 29.9 Regular uterine contractions three times in ten minutes Cervical dilation of at least 3–4 centimeter Informed consent ; allergy to oleaster and lavender Skin infection or lesion in the massage area History of pregnancy or delivery complications Use of herbal medications during or before delivery Use of other non-pharmacological methods for reducing labor pain Any maternal disability Having a midwife or doula Maternal addiction psychiatric disorder Occurrence of a stressful event in the past 6 months assisted reproductive techniques Pregnancy or medical complications such as preeclampsia, diabetes, active bleeding, severe cardiac disorders

Intervention groups
Intervention:massage with oleaster oil;Control:massage with lavender oil

Main outcome variables
Labor pain intensity;Labor anxiety intensity

General information

Reason for update
Conversion from two centers to one center

Acronym

IRCT registration information
IRCT registration number: **IRCT20260205068764N1**
Registration date: **2026-05-25, 1405/03/04**
Registration timing: **prospective**

Last update: **2026-06-14, 1405/03/24**
Update count: **1**

Registration date
2026-05-25, 1405/03/04

Registrant information

Name
Simin Ashrafi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 5523 7271

Email address
ashrafisimin5@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-06-09, 1405/03/19

Expected recruitment end date
2026-09-20, 1405/06/29

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of massage with Elaeagnus angustifolia oil and massage with lavender oil on anxiety and labor pain in pregnant women

Public title

Comparison of the effects of massage with Elaeagnus angustifolia oil and massage with lavender oil on anxiety and labor pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

A healthy, alive, single fetus with no anomalies The mother has no pregnancy-related or medical complications such as preeclampsia, diabetes, active bleeding, or severe cardiac disorders that would prevent massage or continuation of natural labor The delivery is the first to the third The estimated fetal weight according to the most recent ultrasound is 2500 to 4000 grams The fetal lie is longitudinal and the presenting part is cephalic The gestational age is between 37 and 41 weeks Body mass index at delivery is between 18.5 and 29.9 Regular uterine contractions three times in ten minutes Cervical dilation of at least 3-4 centimeters Informed consent to participate in the research

Exclusion criteria:

History of allergy to oleaster (Elaeagnus angustifolia) and lavender Skin infection or lesion in the massage area History of infertility or use of assisted reproductive technique Occurrence of a stressful event in the past 6 months (such as divorce, death of first-degree relatives of the mother Psychiatric disorder based on maternal self-report Maternal addiction by maternal self-report Having an accompanying midwife or doula Any maternal disability (blindness, deafness, hearing loss, motor impairment Use of other non-pharmacological methods for reducing labor pain Use of herbal medications during or before delivery History of pregnancy or delivery complications (neonatal death, dystocia, stillbirth

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The method is as follows: first, six possible blocks (BAAB, ABBA, BABA, BBAA, ABAB, AABB) are listed, and each block is assigned a number from 1 to 6. Then, using a random number table in Excel, a number between 1 and 6 is randomly selected, and participants are allocated to groups according to the block corresponding to that number. This process is repeated until the total sample size is reached. Allocation concealment is performed by an individual, and to conceal the allocation method, the blocks are placed in sealed envelopes. Furthermore, to ensure homogeneity between the two groups regarding the number of primiparous women, participants are stratified based on their current delivery status (first delivery, etc.). The block randomization method is then implemented within each stratum

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

Street address

Gonabad, side of Asian Road

City

Gonabad

Province

Razavi Khorasan

Postal code

۹۶۷۱۹۷۵۸۲۰

Approval date

2026-05-15, 1405/02/25

Ethics committee reference number

IR.GMU.REC.1405.016

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

2

Description of health condition studied

Labor pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Labor pain intensity
Timepoint
before the intervention
Method of measurement
Visual Analogue Scale

2

Description
Labor pain intensity
Timepoint
after the intervention at dilation of 3–4 cm
Method of measurement
Visual Analogue Scale

3

Description
Labor pain intensity
Timepoint
after the intervention at dilation of 5-7cm
Method of measurement
Visual Analogue Scale

4

Description
Labor pain intensity
Timepoint
after the intervention at dilation of 8-10cm
Method of measurement
Visual Analogue Scale

5

Description
Anxiety intensity
Timepoint
Before the intervention
Method of measurement
Visual Analogue Scale

6

Description
Anxiety intensity
Timepoint
after the intervention at dilation of 3–4 cm
Method of measurement
Visual Analogue Scale

7

Description
Anxiety intensity
Timepoint
after the intervention at dilation of 5-7 cm
Method of measurement
Visual Analogue Scale

8

Description
Anxiety intensity
Timepoint
after the intervention at dilation of 8-10 cm
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention groupMassage with 10 drops of oleaster oil from Giahe Kala Company, which has the Sib-e Salamat (health mark) and necessary health permits, is 100% pure and organic, free from additives and preservatives, packaged in antibacterial containers with a volume of 30 cc. The massage will be performed using effleurage (gentle rubbing) with moderate pressure. Simultaneously with the onset of contractions, the mother will be placed in a side-lying position, and a full-back massage will be given for 20 minutes during three stages of cervical dilation: 3–4 cm, 5–7 cm, and 8–10 cm
Category
Treatment - Drugs

2

Description
Control group:Massage with 10 drops of lavender oil from Giahe Kala Company, which has the Sib-e Salamat (health mark) and necessary health permits, is 100% pure and organic, free from additives and preservatives, packaged in antibacterial containers with a volume of 30 cc. The massage will be performed using effleurage (gentle rubbing) with moderate pressure. Simultaneously with the onset of contractions, the mother will be placed in a side-lying position, and a full-back massage will be given for 20 minutes during three stages of cervical dilation: 3–4 cm, 5–7 cm, and 8–10 cm
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Allameh Bohlool Hospital of Gonabad
Full name of responsible person
Simin Ashrafi
Street address
Here is the English translation of the address starting

from the end (reverse order): **"Allameh Bohlool Gonabadi Hospital, Parastar Boulevard, Saadi Street

City
Gonabad

Province
Razavi Khorasan

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9671975820

Phone
+98 51 5723 6832

Email
ashrafisimin5@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person
Dr. Mohammad Amin Momen Moghaddam

Street address
Vice-Chancellery for Education and Research, Gonabad University of Medical Sciences, on the margin of the Asian Highway

City
Gonabad

Province
Razavi Khorasan

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9671974116

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+98 51 5722 3028

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Grant name

Grant code / Reference number

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

Title of funding source
Gonabad 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
Gonabad University of Medical Sciences

Full name of responsible person
Simin Ashrafi

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
No. 32, Second Floor, Second Door on the Left, Emam Reza 26, Jomhouri 40

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ashrafisimin5@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person
Simin Ashrafi

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Simin Ashrafi

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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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