

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Oct 2026

A comparative study of aromatherapy with rosewater and warm shower on the pain intensity of the active phase of labor in primiparous pregnant women.

Protocol summary

Study aim

The effect of aromatherapy with rosewater and warm shower on the intensity of active labor pain in primiparous women

Design

This study is a randomized controlled clinical trial with a parallel design (Phase II). The sample size is 108 participants (36 in each group). Participants will be randomly assigned to three groups. For this purpose, cards labeled A (aromatherapy with rosewater), B (warm shower), and C (control) will be prepared, and each participant will randomly select one card. The intensity of labor pain will be measured at cervical dilations of 4, 6, and 8 centimeters using the Visual Analogue Scale (VAS).

Settings and conduct

The study will be conducted at Gharazi Hospital in Malayer. Eligible participants will be screened and provide written informed consent, then randomly assigned to one of three groups using cards labeled A (aromatherapy), B (warm shower), and C (control). The primary outcome is labor pain intensity. To minimize bias, the outcome assessor will be blinded and will not be aware of group allocation.

Participants/Inclusion and exclusion criteria

Inclusion: Primiparous women aged 18-35, 37-42 weeks gestation, singleton, cephalic presentation, active labor (3-4 cm dilation), normal fetal heart rate. Exclusion: Drug addiction, Intrauterine growth restriction, Diagnosed mental or anatomical disorder, allergy to rose water

Intervention groups

The intervention in the first group was 20 minutes of inhale the aroma of rose water at dilations of 4 cm, 6 cm, and 8 cm. In the second group, a hot shower with a temperature of 38-40 degrees was used in the lumbar and sacral region for 20 minutes at final dilations of 4 cm, 6 cm, and 8 cm. Routine maternity care is also used in the control group.

Main outcome variables

The intensity of labor pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241110063652N3**

Registration date: **2025-10-17, 1404/07/25**

Registration timing: **registered_while_recruiting**

Last update: **2025-10-17, 1404/07/25**

Update count: **0**

Registration date

2025-10-17, 1404/07/25

Registrant information

Name

zahra kohzad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-17, 1404/07/25

Expected recruitment end date

2026-03-16, 1404/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A comparative study of aromatherapy with rosewater and warm shower on the pain intensity of the active phase of labor in primiparous pregnant women.

Public title
The effect of aromatherapy with rosewater and hot showers on the intensity of pain in the active phase of labor in pregnant women

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Primiparous women Women at the beginning of the active phase of labor Gestational age 37-42 weeks Singleton fetus Showing the embryo series
Exclusion criteria:
Fetal heart defect Drug addiction Intrauterine growth restriction Diagnosed mental or anatomical disorder

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **108**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples are randomly assigned to three groups by a third party who is not involved in the research protocol. On three cards marked with the letters C-A-B, where card A represents the aromatherapy with rosewater group, card B represents the hot shower group, and card C represents the control group. The samples are randomly assigned to three groups. The first patient to enter the study is given three cards, chooses Wiki, and is placed in one of the groups. The second is given two cards and is placed in one of the groups, and finally the third is placed in the third group, and from then on the samples are randomly placed in the three groups.

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 Hamadan University of Medical Sciences

Street address

Central Headquarters of Hamadan University of Medical Sciences, Shahid Fahmideh Blvd.

City

Hamadan

Province

Hamadan

Postal code

6517838736

Approval date

2025-10-04, 1404/07/12

Ethics committee reference number

IR.UMSHA.REC.1404.569

Health conditions studied

1

Description of health condition studied

Delivery

ICD-10 code

O80

ICD-10 code description

Encounter for full-term uncomplicated delivery

Primary outcomes

1

Description

Pain

Timepoint

Time points of primary outcome measurement: The intensity of labor pain will be measured at cervical dilatation of 4 cm, 6 cm, and 8 cm using the Visual Analogue Scale (VAS).

Method of measurement

Visual pain scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, participants were exposed to rose water aroma inhalation during three stages of labor, at cervical dilations of 4, 6, and 8 cm. In each stage, the participant sat in a comfortable semi-seated position and inhaled the natural aroma of rose water for 20 minutes through

normal breathing. Five drops of pure rose water 100% concentration, without chemical additive, were applied to a cotton ball placed in a small glass container approximately 30 cm from the participant's nose to allow gradual evaporation. Room temperature was maintained between 24–26°C. The total exposure time was 60 minutes per participant, and no other pharmacological intervention was administered concurrently.

Category

Other

2

Description

Intervention group: In the second intervention group, participants received warm water showers directed to the lumbar and sacral areas during active labor at cervical dilations of 4, 6, and 8 cm. Each session lasted 20 minutes, for a total of 60 minutes per participant. Water temperature was maintained between 38–40°C using a thermometer. A handheld shower device with medium water pressure was used, held approximately 30 cm from the skin. Participants were in a comfortable seated or standing position, and a trained midwife continuously monitored water temperature and safety throughout the procedure.

Category

Other

3

Description

Control group: In the control group, participants received standard routine labor care, which included monitoring of maternal and fetal vital signs according to hospital protocol, assessment of labor progress, emotional support, non-pharmacological comfort measures (such as position changes and breathing techniques), and administration of medications if prescribed by the attending physician. No complementary interventions such as aromatherapy or hydrotherapy were applied in this group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Gharazi Malayer Hospital

Full name of responsible person

Zahra Kahzad

Street address

Opposite Melal Park, Above Nabuwat Square

City

Malayer

Province

Hamadan

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65718-64953

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Alireza Soltanian

Street address

5th Floor, Central Headquarters of Hamadan University of Medical Sciences, Pajhohesh Square, Shahid Fahmideh Blvd.

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Zahra Kohzad

Position

Faculty instructor

Latest degree

Master

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