Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Citrus aurantium Aroma on Anxiety and Duration of Labor Stages in Nulliparous Women

Protocol summary

Study aim
Determining the effect of orange blossom aroma on anxiety and labor duration in first-time mothers.

Design
A randomized, controlled, parallel, and labeled intervention clinical trial, phase 3, on 100 primiparous women. Randomization was performed using the blockrand package in R software.

Settings and conduct
Participants will be randomly assigned to aromatherapy (intervention) or placebo (control) groups. The 6-month study includes interview, observation, examination, demographic and obstetric forms. The Spielberger questionnaire will be completed before intervention and at two dilations, and labor stages will be measured by partograph. A randomized controlled clinical trial on primiparous women at Khorramabad Social Security Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: Iranian primiparous women with gestational age 37–42 weeks and cephalic fetal presentation. Exclusion criteria: Medical or obstetric complications, use of anti-anxietydrugs, allergy or olfactory disorders, use of analgesics or anxiolytics within 3 hours before intervention, addiction to tobacco, drugs, or alcohol, need for emergency cesarean section, need for pharmacological or non-pharmacological pain relief methods, and major stressful events during the past 3 months.

Intervention groups
All primiparous pregnant women مراجعه‌کننده به the maternity ward of Social Security Hospital of Khorramabad in the year 1405 will be included

Main outcome variables
Anxiety, duration of labor stages

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260514069397N1**
Registration date: **2026-06-02, 1405/03/12**
Registration timing: **prospective**

Last update: **2026-06-02, 1405/03/12**
Update count: **0**

Registration date
2026-06-02, 1405/03/12

Registrant information
Name
shahrzad aminian
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 66 3322 1619
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shahrzadaminian793@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-07-20, 1405/04/29

Expected recruitment end date
2026-11-20, 1405/08/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Citrus aurantium Aroma on Anxiety and Duration of Labor Stages in Nulliparous Women

Public title
The Effect of Citrus aurantium Aroma on Anxiety and Duration of Labor Stages in Nulliparous Women
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Iranian ethnicity Primiparous Singleton pregnancy with a gestational age of 37 to 42 weeks Maternal age between 18 and 35 years Cervical dilation of 3–4 cm At least 2 to 3 spontaneous uterine contractions lasting 40–45 seconds within 10 minutes Regular fetal heart rate between 110 and 160 beats per minute Normal maternal vital signs Normal fetal movements according to the mother's report Body mass index of 18.5–29.9 kg/m² Height greater than 145 cm Estimated fetal weight between 2500 and 4000 g Compatibility of the fetal head with the maternal pelvis Consistency of fundal height with gestational age Cephalic fetal presentation Intact amniotic sac
Exclusion criteria:
Presence of medical and obstetric complications in the current pregnancy Use of anti-anxiety medications and supplements Fetal distress or disorder in labor progression Development of sensitivity to orange blossom essential oil Presence of olfactory disorders, allergies, or previous unpleasant experiences with specific scents Use of analgesic or anti-anxiety medication at least 3 hours before the start of the intervention Addiction to tobacco, narcotics, or alcoholic beverages Presence of any contraindication to vaginal delivery Need for labor augmentation with oxytocin or other methods Need for emergency cesarean section Need to use other pharmacological or non-pharmacological pain relief methods Experiencing a major adverse event during the past 3 months
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants enrolled in the study will be allocated to study groups using the permuted block method. Block sizes of 4 and 6 will be considered. Randomization will be performed using the blockrand package in R software.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
"Ethics Committee of Lorestan University of Medical Sciences
Street address
Moallem St., Anoushirvan Rezaei Square, Lorestan University of Medical Sciences Headquarters
City
khoramabad
Province
Lorestan
Postal code
8197978133
Approval date
2026-05-12, 1405/02/22
Ethics committee reference number
IR.LUMS.REC.1405.083

Health conditions studied

1

Description of health condition studied
Anxiety and the duration of labor stages
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Intensity of anxiety during the first stage of labor
Timepoint
Before aromatherapy and twice after the intervention at dilations of 3 to 4 and 6 to 8 cm.
Method of measurement
Spielberger Anxiety Assessment Questionnaire

2

Description
Labor time
Timepoint
Every one to two hours
Method of measurement
Examination and registration in the examination form

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: . In the intervention group, 4 drops of spring orange essential oil are added to 300 ml of water and in the control group, 4 drops of normal saline are added to 300 ml of water and are continuously diffused through an aroma diffuser throughout the entire labor process. Anxiety intensity will be measured 30 minutes after aromatherapy at 3-4 and 6-8 cm dilations. The duration of labor will be measured from 3-4 cm dilation to 10 cm, from 10 cm dilation to delivery of the baby, and from delivery of the baby to delivery of the placenta in both groups.

Category
Treatment - Drugs

2

Description
Control group: In the control group, 4 drops of normal saline are poured into 300 ml of water and continuously diffused through an aroma diffuser throughout the entire duration of labor, and the intensity of anxiety will be measured 30 minutes after aromatherapy at dilations of 3-4 and 6-8 cm. The duration of labor will be measured from dilation of 3-4 cm to 10 cm, from dilation of 10 cm to delivery of the baby, and from delivery of the baby to delivery of the placenta in both groups.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Social Security Hospital

Full name of responsible person
Shahrzad Aminian

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2nd km of Andimeshk Road, East Goldasht

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Khoramabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
Dr Peyman Astaraki

Street address
Kamalvand University Complex, Faculty of Nursing Campus

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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
Khoram-Abad 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
Khoram-Abad University of Medical Sciences

Full name of responsible person
Soheila Pirdade Beyranvand

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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