Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Comparative the effect of auriculotherapy and aromatherapy with Citrus aurantium aroma on intensity of labour pain and some variables of maternal and neonatal outcomes in primiparous women: A Double Blinded Randomized Controlled Trial

Protocol summary

Study aim

Comparison of the effect of auriculotherapy and aromatherapy with Citrus aurantium on the labor pain intensity and some variables of maternal and neonatal outcomes

Design

Sampling method: available Randomization with permuted blocks will be used to allocate the samples to three groups. 138 samples will be placed in 23 blocks of 6 and the random allocation list will be done by Random Allocation software. The sample size was determined with G*Power software with a power of 80% and α = 0.05 (type 1 error) and using the same information of previous article (effect size 0.625). Finally, 46 samples will be determined in each group, taking into account the 10% attrition.

Settings and conduct

Sampling will be done by the available method in the active phase of labor and in the labor department by dividing the participants into three groups: auriculotherapy, aromatherapy and control. The outcome assessor and the participants will be blinded due to not knowing which group the participants will be in.

Participants/Inclusion and exclusion criteria

Iranian primiparous women aged 18 to 35 who had an uncomplicated pregnancy

Intervention groups

In the aromatherapy group, gauze impregnated with Citrus aurantium will be attached to their collars, and seedless adhesives are attached to four points of ears. In the auriculotherapy group, adhesives with Vacaria seeds are attached to the primary and essential points of two ears. Also, gauze soaked in distilled water will be attached to their collar . In the control group, seedless adhesives will be applied to four unrelated points in both ears. In addition, gauze soaked with distilled water will be attached to their collars. Meanwhile, all three groups will receive the usual maternity care.

Main outcome variables

labor pain intensity, anxiety intensity, length of the active phase, length of the second stage, Apgar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231212060342N1**
Registration date: **2023-12-29, 1402/10/08**
Registration timing: **prospective**

Last update: **2023-12-29, 1402/10/08**
Update count: **0**

Registration date

2023-12-29, 1402/10/08

Registrant information

Name

Fatane Eeftekhari Shah Abad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

eftekhary.fatane@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-30, 1402/10/09

Expected recruitment end date
2024-08-20, 1403/05/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative the effect of auriculotherapy and aromatherapy with Citrus aurantium aroma on intensity of labour pain and some variables of maternal and neonatal outcomes in primiparous women: A Double Blinded Randomized Controlled Trial

Public title
Comparative the effect of auriculotherapy and aromatherapy with Citrus aurantium aroma on intensity of labour pain and some variables of maternal and neonatal outcomes in primiparous women: A Double Blinded Randomized Controlled Trial
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Iranian women Prim parous women Having minimum literacy that is able to read and write Term pregnancy Singleton pregnancy with an alive fetus A fetus with cephalic presentation A fetus with an approximate weight of less than 4 kg Start of spontaneous labor contractions 4 cm dilation of the cervix A pelvis with suitable dimeters for childbirth Intact amniotic membranes Written Informed consent to participate in this study Bilateral external ear without any lesion (mass, swelling, infection or wound) for doing auriculotherapy
Exclusion criteria:
Use of painkillers in the last eight hours Using any complementary or traditional medicines to start labor pain Diagnosed liver, gall bladder or respiratory diseases Chronic diabetes or gestational diabetes Olfactory disorders in the aromatherapy group Allergy to herbal medicines for the aromatherapy group Allergy to Citrus aurantium in the aromatherapy group Pregnancy complications (such as pre-eclampsia, chorioamnionitis, placental abruption and abnormal fetal heart rate, etc.)
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **138**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomization, permutation block method will be used to allocate samples to three groups (no intervention - auriculotherapy group - aromatherapy group) , 138 samples will be placed in 23 blocks of 6. Random allocation list is provided by Random software.
Blinding (investigator's opinion)
Double blinded
Blinding description
In the aromatherapy group, gauze impregnated with 4 drops of citrus aurantium aroma (Adonis Gol Daru Company-Iran) will be attached to the neck of the participants. gauzes will be changed every 30 minutes until the cervix has reached 10 centimeters dilation. In addition, in order to avoid bias, for all participants in the aromatherapy group, grain-free adhesives will be applied on four unrelated points (ankle, knee, tooth and jaw) of both ears. Then every 30 minutes in between uterus contraction, a gentle palpation is placed on one of the ears by the project manager, but these points will not be pressed. In the auriculotherapy group, pressure on the main points of the ear in the external ear (point zero, shen men, sympathetic, thalamus) with the aim of reducing pain and anxiety and the primary points of the ear (uterus (C), uterus (E), Gonadotrophins, ovaries, pelvis , abdomen) with the aim of reducing pain and helping the progress of labor, is applied by a trained researcher who has completed the preliminary auriculotherapy course in 22 hours under the supervision of the Iranian Midwifery Association. To avoid creating bias, auriculotherapy is performed by one person for all research subjects. First, the right ear is cleaned using alcohol, pressure is applied using adhesives containing vacaria seeds for auriculotherapy by ZhongyanTaihe Company, which is available in the Iran, for 30 seconds between contractions, and finger pressure is applied on the vacaria seeds. After 30 minutes, the same points in the left ear are pressed for 30 seconds between contractions, and with finger pressure on the Vacaria seeds. The seeds are compressed alternately on the right and left ear every 30 minutes and each time for 30 seconds until the time of dilation of 10 cm. Finger pressure on the seeds to the extent that the pain is tolerable for the samples. In order to avoid bias, in the auriculotherapy group, a moisten gauze with 4 drops of distilled water will be attached to the collar of all participants. gauzes will be changed every 30 minutes until 10 cm dilation For all participants in the control group, seedless adhesives will be applied on four unrelated points (ankle, knee, tooth and jaw) of both ears. Then, every 30 minutes, a gentle hand is placed on one of their ears, but these points will not be pressed. In addition, for all participants in this group, gauze soaked with 4 drops of distilled water will be attached to their collars. Gauzes will be changed every 30 minutes until 10 cm dilation. Also, all three groups will receive the usual maternity care. For blinding, the outcome evaluator and the participants will not be informed of which group each sample belongs to, and only the project manager who performs the necessary interventions in the labor and delivery room will know about the groups.
Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Schools of Nursing and Midwifery, Management and Medical Information s

Street address

Faculty of Nursing and Midwifery, Namazi Hospital, Namazi Square, Shiraz

City

Shiraz

Province

Fars

Postal code

۷۱۹۳۶۱۳۱۱۹

Approval date

2023-10-28, 1402/08/06

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1402.105

Health conditions studied

1

Description of health condition studied

Labor pain intensity

ICD-10 code

O94-O99

ICD-10 code description

Other obstetric conditions, not elsewhere classified

2

Description of health condition studied

Labor anxiety

ICD-10 code

O94-O99

ICD-10 code description

Other obstetric conditions, not elsewhere classified

3

Description of health condition studied

Active phase length of delivery

ICD-10 code

O80-O84

ICD-10 code description

Delivery

Primary outcomes

1

Description

Labor pain intensity

Timepoint

The intensity of labor pain in all three groups will be measured at 4 cm dilatation (before the start of the intervention) and 20 minutes after the start of the intervention at 4 cm dilation as well as at 6 and 8 cm.

Method of measurement

To determine the intensity of labor pain, the visual analog scale of pain measurement (VAS) will be used.

2

Description

Anxiety

Timepoint

The intensity of anxiety in all three groups will be measured at 4 cm dilation (before the start of the intervention) and 20 minutes after the start of the intervention at 4 cm dilation, as well as at 6 and 8 cm.

Method of measurement

The intensity of anxiety will be measured with the Spielberger state-trait anxiety questionnaire.

3

Description

The length of the active phase

Timepoint

The time interval between4 cm dilatation to full cervical dilatation in the presence of at least 2 contractions in 10 minutes will be calculated based on hours and minutes during labor.

Method of measurement

In order to measure the length of the active phase of labor, the partograph diagram is drawn in the delivery room and the length of the active phase of labor will be calculated by the researcher.

Secondary outcomes

1

Description

Length of the second stage of labor

Timepoint

The length of this stage will be measured by the researcher by measuring the time interval between the complete dilatation of the cervix and the exit of the fetus in minutes.

Method of measurement

The length of this stage will be measured by the researcher with measuring the time of between the complete dilatation of the cervix and the exit of the fetus in minutes.

2

Description
Apgar Score
Timepoint
Apgar score will be calculated in the first and fifth minutes after birth.
Method of measurement
The Apgar table will be used to calculate the Apgar score.

Intervention groups

1

Description
Intervention group: In the aromatherapy group, gauze impregnated with 4 drops of Citrus aurantium aroma (Adonis Gol Daru Company-Iran) will be attached to the participants' collars. Gauzes will be changed every 30 minutes until 10 cm dilation. In addition, in order to avoid bias, for all participants in the aromatherapy group, grain-free adhesives will be applied on four unrelated points (ankle, knee, tooth and jaw) of both ears. Then every 30 minutes and between uterine contractions, a gentle hand is placed on their ears, but these points will not be pressed.
Category
Treatment - Other

2

Description
Intervention group: In the auriculotherapy group, pressure on the main points of the ear in the external ear (point zero, shen men, sympathetic, thalamus) with the aim of reducing pain and anxiety and the primary points of the ear (uterus (C), uterus (E), Gonadotrophins, ovaries, pelvis, abdomen)) with the aim of reducing pain and helping the progress of labor, is applied by a trained researcher who has completed the preliminary course of auriculotherapy in 22 hours under the supervision of the Iranian Midwifery Scientific Association. To prevent torsion, ericulotherapy is performed by one person for all research samples. First, the ears are cleaned using alcohol and is applied adhesives containing vacaria seeds for auriculotherapy by ZhongyanTaihe Company, which is available in the Iran . For 30 seconds between contractions, and finger pressure is applied on the vacaria seeds of right ear. After 30 minutes, the same points in the left ear are pressed for 30 seconds between contractions, and with finger pressure on the Vacaria seeds. The seeds are compressed alternately on the right or left ear every 30 minutes and each time for 30 seconds until the full dilation. Finger pressure on the seeds to the extent that the pain is bearable for the client. In order to avoid bias, in the auriculotherapy group, gauze impregnated with 4 drops of distilled water will be attached to the collar of all participants. Gauzes will be changed every 30 minutes until 10 cm dilation.
Category
Treatment - Other

3

Description
Control group: For all participants in the control group, seedless adhesives will be applied on four unrelated points (ankle, knee, tooth and jaw) of both ears. Then, every 30 minutes, a gentle hand is placed on one of their ears, but these points will not be pressed. In addition, for all participants in this group, a gauze soaked with 4 drops of distilled water will be attached to their collars. Gauzes will be changed every 30 minutes until 10 cm dilation
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi University of Medical Sciences, Yazd
Full name of responsible person
Dr. Seyed Mehdi Hashemi Bajgani
Street address
Central Building of Shahid Sadougi University of Medical Sciences, Bahonar Square, Yazd
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Yazd
Province
Yazd
Postal code
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Phone
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Email
info@ssu.ac.ir
Web page address
https://ssu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Seyed Vahid Hosseini
Street address
The central building of Shiraz University of Medical Sciences, in front of Palestine Street, Zand Street, Shiraz
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Shiraz
Province
Fars
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Phone
+98 71 3230 5410
Email

info@sums.ac.ir

Web page address

https://sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Fatane Eeftekhari Shah Abad

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Postal code

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

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Other areas of specialty/work

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Shiraz

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Fatane Eeftekhari Shah Abad

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

The second door on the left, the second dead end on the right, Arash Ik Alley, Forty Alley, Ayatollah Khamenei Blvd., Yazd City

City

Yazd

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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