Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of lavender and clove essential oil on the intensity of pain and anxiety of the first stage of labor

Protocol summary

Study aim
Determining and comparing the effect of lavender and clove essential oil on the intensity of pain and anxiety in the first stage of labor

Design
Clinical trial with control group, with parallel groups, single blind, phase3 on 159 people, random block allocation of samples

Settings and conduct
The study will be conducted in the maternity hospitals of AllamehBahloul Gonabadi Gonabad and Hashminejad Hospitals in Mashhad.After explaining and obtaining informed consent, the eligible samples are randomly divided into three aromatherapy groups with lavender, cloves and distilled water (control group).Completion of individual and midwifery questionnaires and checklist of observation and examination and aromatherapy are performed in 4-5 cm dilatation by connecting gauze impregnated with 0.2 cc of 2% solution to the collar of the samples and repeating every 15 minutes.Pain intensity(VAS) and anxiety intensity(Spielberger) are measured twice at 4-5cm dilation and 8-10cm dilation.The samples are blind of the prescribed essential oil type.

Participants/Inclusion and exclusion criteria
Inclusion criteria: -Women with first and second pregnancy -Having informed consent -Gestational age 38-42w -Cervix dilatation more than 3cm -Normal Vaginal Delivery -No history of asthma, allergy and sensitivity to herbal medicines and smell problems -Absence of pregnancy and obstetrics complications -Not suffering from known anxiety and depression and migraine -Not receiving medical painkillers 3 hours before the start of the intervention Exclusion criteria: -Non-cooperation of the mother -Leaving the natural course or emergency caesarean section -Allergic to essential oil

Intervention groups
Three intervention groups include aromatherapy with lavender essential oil, clove essential oil and distilled water

Main outcome variables
Intensity of pain and anxiety in the first stage of childbirth

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230301057585N1**
Registration date: **2023-03-10, 1401/12/19**
Registration timing: **prospective**

Last update: **2023-03-10, 1401/12/19**
Update count: **0**

Registration date
2023-03-10, 1401/12/19

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-04, 1402/01/15

Expected recruitment end date
2023-07-22, 1402/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of lavender and clove essential oil on the intensity of pain and anxiety of the first stage of labor

Public title

Comparison of the effect of aromatherapy with lavender and clove essential oil on labor pain and anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Women with first and second pregnancy, aged 18-35 years, pregnant with single fetus , having a normal delivery, 38-42 weeks of pregnancy, cephalic presentation, cervical dilatation more than 3 cm. No history of asthma, sensitivity and allergy according to mother's statements. Absence of disease and complications of pregnancy and obstetrics (such as: pre-eclampsia - chorioamnionitis - known liver, gallbladder and respiratory disease, decollement and abnormal heartbeat of the fetus at the beginning of the study), Not having smell problems and allergies to herbal medicines according to the person. Not having a known anxiety and depression disease according to the person's statements in the medical history and the mother's file. Not having migraines according to the mother's statements in the medical history. Not receiving medical painkillers 3 hours before the start of the study. There is no history of infertility and thyroid disease according to the person's statements in the medical history and the mother's file. Informed consent of women to participate in the study

Exclusion criteria:

Mother's non-cooperation in completing the checklist and expressing her pain Departure from the natural course of labor Having an emergency caesarean section Allergic to essential oil Fetal weight less than 2.5 kg or more than 4 kg

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **159**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples of this study are selected using an easy and accessible sampling method And to allocate the samples to the studied groups, the block random allocation method will be used.For this purpose, the "blockran" package was used in R statistical software.In the relevant function in this package, the number of treatments was 3 and the volume of the block was 6, and then the studied samples were assigned to groups using the random sequence generated by the random blocks of 6.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the participants are aware of the intervention, but they do not know the type of essential oil they are prescribed (lavender, clove or distilled water).

Placebo

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

No. 514, North Building, Parsian Tower, Amoozegar 37 Ave, Amoozegar Blvd, Mashhad City

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Mashhad

Province

Razavi Khorasan

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Approval date

2023-02-13, 1401/11/24

Ethics committee reference number

IR.GMU.REC.1401.184

Health conditions studied

1

Description of health condition studied

pain and anxiety of the first stage of labor

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Labor Pain score

Timepoint

At the beginning of the study, dilation 4-5 cm , dilatation 8-10 cm

Method of measurement
Visual Analogue Scale (VAS)

2

Description
Anxiety score
Timepoint
At the beginning of the study, dilation 4-5 cm , dilatation 8-10 cm
Method of measurement
Spielberger anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention group: Aromatherapy with lavender essential oil with a concentration of 2% was purchased from Barich Essential Oil Company, which is impregnated with gas to the extent of 0.2 cc and attached to the collar of the participants' clothes, and its prescription is repeated every 15 minutes, and they are asked to breathe normally.
Category
Treatment - Drugs

2

Description
Second Intervention group: Aromatherapy with clove essential oil with a concentration of 2% was purchased from Barich Essential Oil Company, which is impregnated with gas to the extent of 0.2 cc and attached to the collar of the participants' clothes, and its prescription is repeated every 15 minutes, and they are asked to breathe normally.
Category
Treatment - Drugs

3

Description
Control group: In the control group, 0.2 cc of distilled water is impregnated with gas and attached to the collar of the participants' clothes, and its prescription is repeated every 15 minutes, and they are asked to breathe normally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad Hasheminezhad hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Information on main outcomes in participant data after de-identification of individuals
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used

The necessary conditions for requesting data include the applicant's profile, the reason for the request, and how to use it.Then the requested items are sent with the opinion of the authors.

From where data/document is obtainable

NiloofarAhmadi97@gmail.com 09151087996 Niloofar SadeghAhmadi

What processes are involved for a request to access data/document

After the applicant's request, the data will be sent via email within 15 days.

Comments