

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

Name

Nilloofar SadeghAhmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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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

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Razavi Khorasan

Postal code

9188173282

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

Niloofer SadeghAhmadi

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Recruitment center**Name of recruitment center**

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

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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

Niloofar SadeghAhmadi

Position

Master of Science student of Midwifery

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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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