# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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**
Niloofar SadeghAhmadi

**Name of organization / entity**

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Iran (Islamic Republic of)

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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

**City**

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**Province**

Razavi Khorasan

**Postal code**

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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

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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
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Niloofar SadeghAhmadi
**Position**
Master of Science student of Midwifery
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Bachelor
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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**