

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

**Clinical trial of Comparison The effect of aromatherapy with essential oil of Rosa damascene and lavender in the single and mixed form on pain, anxiety and duration of first and second stages of labor in primigravida women.**

### Protocol summary

#### Summary

This study is a randomized blind clinical trial study to compare the effect of aromatherapy with essential oil of Rosa damascena and lavender in the single and mixed form on pain intensity, anxiety level and used during the first and second stages of Labour in primigravida women. The study population consisted of all pregnant women who were admitted to delivery wards in Zahedan. 120 pregnant women eligible for the study sample were selected and then the draw up and randomly selected the units in to four groups (inhalation of rose, lavender, combining rose and lavender and inhalation of distilled water. ) and 30 patients were in each group. The day when the patients were studied the pain intensity using the Visual Analogue Scale (VAS) was reviewed. Then poured oil on the gauze and clipped to the women collars and were asked to inhale their fragrance during uterine contractions. Again pain intensity was measured 30 and 60 minutes after the beginning of the study. In the control group distilled water was used instead of oil, and the intensity of pain was studied in other groups.

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2017012323370N4**  
Registration date: **2017-04-23, 1396/02/03**  
Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2017-04-23, 1396/02/03

#### Registrant information

##### Name

Maryam Navaee

##### Name of organization / entity

Nursing and Midwifery Faculty

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3344 4510

##### Email address

navaee.m@zamuc.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Zahedan University of Medical Sciences

#### Expected recruitment start date

2014-03-20, 1392/12/29

#### Expected recruitment end date

2015-03-20, 1393/12/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Clinical trial of Comparison The effect of aromatherapy with essential oil of Rosa damascene and lavender in the single and mixed form on pain, anxiety and duration of first and second stages of labor in primigravida women.

#### Public title

effect of aromatherapy on pain, anxiety and duration of first and second stages of labor

#### Purpose

Supportive

**Inclusion/Exclusion criteria**

Inclusion criterias: Age between 18-35; Normal pregnancy between 42-38 weeks; Cephalic presentation; Normal fetus and amniotic fluid index; Singleton pregnancy; Dilatation of the cervix 3-4 cm, At least the fifth class of the primary education and no history of infertility; The absence of acute and chronic diseases; Asthma, eczema and allergies; Lack of anxiety and known depression diseases; Not taking anti-anxiety drugs; No addiction to narcotic drugs; Since last six months had no severe emotional disorders; And they shouldn't be from the medical staff. Exclusion criterias: Receiving analgesics; Sedatives and narcotics drugs with in three hours of the beginning and during the study; Use of oxytocin for induction and augmentation of Labour; All mothers who were discharged the natural course of Labour and were in need of intensive care or emergency cesarean section, Or had allergy to the used material.

**Age**

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

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Vice chancellor for research, Zahedan University of Medical Sciences

**Street address**

Zahedan University of Medical Sciences, Khalije Fars Boulevard, Zahedan, Ira

**City**

Zahedan

**Postal code**

98167-43463

**Approval date**

2014-07-13, 1393/04/22

**Ethics committee reference number****Health conditions studied****1****Description of health condition studied**

pain and anxiety and duration of first and second stages of labor

**ICD-10 code**

O60-75

**ICD-10 code description**

Complications of labour and delivery

**Primary outcomes****1****Description**

Anxiety

**Timepoint**

At the beginning of the active phase and before the intervention and again after giving birth

**Method of measurement**

With anxiety inventory Spillberger

**2****Description**

Pain

**Timepoint**

30 and 60 minutes after intervention

**Method of measurement**

Using a numerical pain scale (VAS)

**3****Description**

First stages of labor

**Timepoint**

Once and from the beginning to the end of the active phase

**Method of measurement**

using a researcher-made questionnaire

**4****Description**

Second stages of labor

**Timepoint**

Once and from the beginning to the end of the active phase

**Method of measurement**

Using a researcher-made questionnaire

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

On the nulliparous women with VAS pain intensity and anxiety level were assessed by questionnaire "Eshpel Burger" into four groups and then intervention was divided into three groups as below. The first group inhaled 0.1 ml rose mixed with 2 ml of distilled water, the second group inhaled 0.1 ml of lavender oil mixed with 2 ml of distilled water, the third group inhaled 0.1 ml Rose and 0.1 ml of lavender oil mixed with 2 ml of distilled water. Then poured oil on the guate and clipped to the collars of the women and asked them to inhale their fragrance during uteral contractions. Pain intensity and anxiety level were measured again 30 and 60 minutes after the intervention. The duration of the first stage and second stage were measured and recorded by the researcher.

### Category

Placebo

## 2

### Description

In the control group ,placebo or normal saline (N/S) was used in the place of oil so that in the active phase of the Labour two drops of saline is poured on the threaded guates. pain intensity is measured by VAS and the anxiety level by questionnaire "Eshpel Burger" 30 and 60 minutes after intervention was measured. The duration of the first and second stage were measured and recorded by the researcher.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Emam Ali Hospital

**Full name of responsible person**

Parvaneh Pahlavan

**Street address**

Khalije Fars Boulevard, Zahedan, Iran

**City**

Zahedan

### 2

#### Recruitment center

**Name of recruitment center**

Nabiakram Hospital

**Full name of responsible person**

Tahereh Rajaee

**Street address**

Motahari Boulevard, Zahedan, Iran

**City**

Zahedan

## 3

### Recruitment center

**Name of recruitment center**

Taamin Ejtemaee Hospital

**Full name of responsible person**

Zahra Saravani

**Street address**

Parastar Square, Zahedan, Iran

**City**

Zahedan

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research, Zahedan University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Taheri

**Street address**

Zahedan University of Medical Sciences, Khhalije fars Square, Zahedan,Iran

**City**

Zahedan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Zahedan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Faculty of Nursing and Midwifery

**Full name of responsible person**

Maryam Navaee

**Position**

Master degree, faculty member

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

*empty*

### Study Protocol

*empty*

### Statistical Analysis Plan

*empty*

### Informed Consent Form

*empty*

### Clinical Study Report

*empty*

### Analytic Code

*empty*

### Data Dictionary

*empty*