

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparison of the effects of aromatherapy with roses and lavender extract on pain and anxiety of active phase of labor in nulliparous women

#### Protocol summary

Anxiety; Labor pain; Normal delivery

#### Study aim

Comparison of the effect of aromatherapy with rose extract and lavender bird extract on the anxiety of delivery active phase in nulliparous women

#### Design

Clinical trials with community-based control group, parallel groups, single-blind and randomized

#### Settings and conduct

This research was carried out at the Maternity ward of Amiralmomenin Hospital in Zabol. The pain intensity of the samples was measured 3 times in dilatation of 4-5cm, 7-8 cm and 8-10 using pain ruler. This study was carried out single blind. Blinding: Interventions in this research are carried out by a researcher and the evaluation form is completed by another person who is not aware of the type of intervention used.

#### Participants/Inclusion and exclusion criteria

Single pregnancy; gestational age 38-42 week; age 18-35; cephalic presentation ; dilatation of more than 3 cm; absence of asthma and allergy; non-complications during pregnancy and lactation; lack of olfactory problems; sensitivity to herbal drugs; lack of anxiety disorder Known depression; Lack of history of infertility and the onset of thyroid disease

#### Intervention groups

There were 3 therapeutic groups in the study: Aromatic scent with rose, lavender, distilled water. Intervention group 1: In the rose group a piece of cloth was impregnated with 0.2 ml of the rose oil and was attached to the collar of the patients and was repeated every 15 minutes. Intervention group 2: In the lavender group a piece of cloth was impregnated with 0.2 ml of lavender essential oil and was attached to the collar of the samples and was repeated every 15 minutes. Control group: 1 drop of distilled water was used and the process was repeated every 15 minutes.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180513039632N1**

Registration date: **2018-06-09, 1397/03/19**

Registration timing: **retrospective**

Last update: **2018-06-09, 1397/03/19**

Update count: **0**

##### Registration date

2018-06-09, 1397/03/19

##### Registrant information

##### Name

Sanaz Nehbandani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3222 8046

##### Email address

snebandani2013@zmbu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-09-22, 1396/06/31

##### Expected recruitment end date

2018-04-20, 1397/01/31

##### Actual recruitment start date

2017-09-22, 1396/06/31

##### Actual recruitment end date

2018-04-20, 1397/01/31

**Trial completion date**

empty

**Scientific title**

Comparision of the effects of aromatherapy with roses and lavender ecxtract on pain and anxiety of active phase of labor in nulliparous women

**Public title**

Studying the Effect of Aromatherapy on Pain and Anxiety

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Gestational age of 38-42 week Being at the age of 18-35 years Cervical dilatation of more than 3 CM Singleton pregnancy

**Exclusion criteria:**

History of asthma and allergies Known liver, gallbladder and respiratory tract disease Complications during pregnancy and maternity Olfactory problems and sensitivity to herbal medicine Anxiety and depression History of infertility and especially thyroid disease

**Age**

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

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization method: Simple randomization. Random unit: Individual. Instrumentation: Using colored cards.

How to make sequences: random

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

All interventions in this research are done by the researcher and the information registration form and the pain assessment scale are completed by another person who are not aware of the type of intervention used.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics committee of Zabol University of Medical Sciences

**Street address**

No8, Taleghani 47, Taleghani street

**City**

Zabol

**Province**

Sistan-va-Balouchestan

**Postal code**

9861784678

**Approval date**

2016-12-24, 1395/10/04

**Ethics committee reference number**

ZBMU.REC.1395.83

**Health conditions studied****1****Description of health condition studied**

Labor pain

**ICD-10 code**

000-099

**ICD-10 code description**

080-084

**2****Description of health condition studied**

anxiety

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

labor pain

**Timepoint**

At the beginning of the study and at 4-5 cm, 6-7 cm and 8-10 cm dilatation

**Method of measurement**

McGill Pain Relief Questionnaire

**2****Description**

Anxiety

**Timepoint**

Before and after intervention

**Method of measurement**

Spielberger Anxiety Inventory

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

First intervention group: Rose concentration 1%, produced by Barij Essen Company. In the rose group a piece of cloth was impregnated with 0.2 ml of the rose oil and was attached to the collar of the patients and patient inhaled the rose smell. This process starts from the onset of the labor active phase and was repeated every 15 minutes.

#### Category

Other

### 2

#### Description

Intervention group 2: The lavender concentration produced by Barij Essen. That was prepared by distillation method with concentration of 1.5% of unopened flowers and olive oil was used as the carrier. In this group, a piece of cloth was impregnated with 0.2 ml of the rose oil and was attached to the collar of the patients and patient inhaled the rose smell. This process starts from the onset of the labor active phase and was repeated every 15 minutes.

#### Category

Other

### 3

#### Description

Control group: Distilled water. A drop of distilled water was stacked on a piece of cloth and was attached to the patient's collar. The process was repeated every 15 minutes.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Zabol Amiralmomenin Hospital

##### Full name of responsible person

Sanaz Nehbandani

##### Street address

Taleghani 47, Taleghani street, Zabol

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##### Province

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snebandani2013@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zabol University of Medical Sciences

##### Full name of responsible person

خدیجه رضایی کیخایی

##### Street address

Zabol Nursing and Midwifery Faculty, Ferdowsi 3, Ferdowsi street

##### City

Zabol

##### Province

Sistan-va-Balouchestan

##### Postal code

9861734184

##### Phone

+98 54 3223 0765

##### Email

snebandani2013@zbm.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Zabol 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

Zabol University of Medical Sciences

##### Full name of responsible person

Sanaz Nehbandani

##### Position

Consultant

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery

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No 8, Taleghani 47, Taleghani street

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##### Province

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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)

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

Not applicable

### Title and more details about the data/document

The main consequences will be published in the article

### When the data will become available and for how long

2018

### To whom data/document is available

Researchers working in academia

### Under which criteria data/document could be used

For scientific research

### From where data/document is obtainable

Sanaz Nehbandani. snehbandani2013@zbmu.ac.ir

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

After getting permission from relevant individuals, there is the possibility of sending data

### Comments