

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Effect of Massage Aromatherapy with Lavender Oil on pain intensity of active phase of labor in nulliparous women.

#### Protocol summary

##### Summary

Objective: The effect of massage aromatherapy with lavender oil on pain intensity of active phase of labor in nulliparous women. Design: randomized, single blind, control with placebo, single center, Phase one trial Method: a) The study population: term pregnant women who admitted to Mahdiyeh Hospital in Tehran city in 2008 that referred to vaginal delivery. 1) The main criteria for inclusion to study: Private consent for the study; age between 18-35; gestational age between 37-42; cephalic presentation; singleton pregnancy; cervical dilatation 4 cm; Iranian race; low-risk pregnancies;  $19/8 < \text{BMI} < 26/4$ . 2) The main criteria for exclusion of study: athletes; addiction to narcotic; use of sedative drugs and also use of oxytocin as induction and augmentation. 3) Sample size: 90 people b) The study interventions: samples of eligible were divided into three groups as massage, massage with Almond oil, massage aromatherapy with lavender oil. Back massage was performed by effleurage. c) The intervention of time: Massage was performed during 20 minutes in the three stages, dilatation 4-5 cm, dilatation 6-7 cm and dilatation 8-10 cm. d) The primary outcome measure: Pain intensity of labor

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201110057727N1**  
Registration date: **2011-11-09, 1390/08/18**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-11-09, 1390/08/18

#### Registrant information

##### Name

Leila Mohammadkhani Shahri

##### Name of organization / entity

Islamic Azad University Karaj Branch

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7724 0711

##### Email address

l.mohamadkhani@gmail.com

#### Recruitment status

##### Recruitment complete

#### Funding source

Ahvaz Jundishapur University Of Medical Sciences

#### Expected recruitment start date

2008-01-21, 1386/11/01

#### Expected recruitment end date

2008-06-20, 1387/03/31

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of Massage Aromatherapy with Lavender Oil on pain intensity of active phase of labor in nulliparous women.

#### Public title

Effect of Lavender on pain of labor

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

The main criteria for inclusion to study: signing informed consent; age between 18-35; gestational age between 37-42; cephalic presentation; singleton pregnancy; cervical dilatation 4 cm; Iranian race; low-risk

pregnancies; 19 / 8 < BMI < 26 / 4. The main criteria for exclusion of study: athletes; addiction to narcotic; use of sedative drugs and also use of oxytocin as induction and augmentation.

#### **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: **90**

#### **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**

Ahvaz Jundishapur University Of Medical Sciences

##### **Street address**

Deputy of Research and Technology, Ahvaz  
Jundishapur University Of Medical Sciences, Golestan  
Ave.- Ahvaz

##### **City**

Ahvaz

##### **Postal code**

61357-33184

#### **Approval date**

2008-01-15, 1386/10/25

#### **Ethics committee reference number**

7/8/600/پ

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Pain of labor

#### **ICD-10 code**

O75.9

#### **ICD-10 code description**

Complication of labour and delivery, unspecified

## **Primary outcomes**

### **1**

#### **Description**

Pain intensity of labor

#### **Timepoint**

Before and after of massage

#### **Method of measurement**

Visual analog scale pain in dilatation 5-4, 7-6 and 10-8 cm has been completed before and immediately after intervention (during contractions) between contractions by assistant in 6 times totally

## **Secondary outcomes**

### **1**

#### **Description**

Satisfaction of intervention

#### **Timepoint**

About 1 to 2 hours after delivery

#### **Method of measurement**

Satisfaction questionnaire

## **Intervention groups**

### **1**

#### **Description**

The intervention Group: The massage aromatherapy group with two drops of lavender oil solute in 50 cc bitter almond oil. Kind of intervention group: drugs. Effloraug massage (rub) was performed gently and in medium press by rhythmic during three stages of dilatation 5-4 cm, dilatation 7-6 cm and dilatation 10-8 cm. These massages were performed in 20 minutes (during the intervals and between contractions). The samples eligible have been massage at all of back in lateral position (semi-prone) and the assistant was standing or sitting.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

The control group: The massage group without lavender oil. Kind of control group: The previous executable program with mentioned specifications. Effloraug massage (rub) was performed gently and in medium press by rhythmic during three stages of dilatation 5-4 cm, dilatation 7-6 cm and dilatation 10-8 cm. These massages were performed in 20 minutes (during the intervals and between contractions). The samples eligible have been massage at all of back in lateral position (semi-prone) and the assistant was standing or sitting.

#### **Category**

Treatment - Other

### 3

#### Description

The control group: The massage group with 15 cc of bitter almond oil. Kind of control group: Placebo. Efflorage massage (rub) was performed gently and in medium press by rhythmic during three stages of dilatation 5-4 cm, dilatation 7-6 cm and dilatation 10-8 cm. These massages were performed in 20 minutes (during the intervals and between contractions). The samples eligible have been massage at all of back in lateral position (semi-prone) and the assistant was standing or sitting.

#### Category

Placebo

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Mahdiyeh Hospital

###### Full name of responsible person

Leila Mohamadkhani Shahri

###### Street address

Fadaeyan Eslam Ave., Shush Square, Tehran

###### City

Tehran

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Ahvaz Jundishapur University Of Medical Sciences

###### Full name of responsible person

Dr Mohammad Reza Abbaspoor

###### Street address

Unit 4, Deputy of Research and Technology, Ahvaz Jundishapur University Of Medical Sciences, Golestan Ave., Ahvaz

###### City

Ahvaz

##### Grant name

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##### Grant code / Reference number

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

Yes

##### Title of funding source

Ahvaz Jundishapur 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

Islamic Azad University Branch Of Birjand

##### Full name of responsible person

Samaneh Sabet Birgandi

##### Position

Master Of University, MS Degree Of Midwifery

##### Other areas of specialty/work

##### Street address

Ayatollah Ghaffari ave., Birjand

##### City

Birjand

##### Postal code

##### Phone

+98 56 1434 2260

##### Fax

+98 56 1434 2171

##### Email

Samane\_Sabet5@yahoo.com

##### Web page address

www.laubir.ac.ir

### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahvaz Jundishapur University Of Medical Sciences

##### Full name of responsible person

Zahre Abbaspoor

##### Position

Master Of University, MS Degree Of Midwifery

##### Other areas of specialty/work

##### Street address

Midwifery Group, Faculty Nursing And Midwifery, Ahvaz Jundishapur University Of Medical Sciences, Golestak Ave.

##### City

Ahvaz

##### Postal code

61357-33184

##### Phone

+98 61 1373 8331

##### Fax

+98 61 1336 1544

##### Email

Industry@ajums.ac.ir, Industry333@yahoo.com

##### Web page address

www.ajums.ac.ir

### Person responsible for updating data

#### Contact

##### Name of organization / entity

Ahvaz Jundishapur University Of Medical Sciences

##### Full name of responsible person

Leila Mohamadkhani Shahri

**Position**

MS Degree of Midwifery, Instructor Of Midwifery

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

Faculty Nursing And Midwifery, Ahvaz Jundishapure  
University Of Medical Sciences, Golestan Ave.

**City**

Ahvaz

**Postal code**

61357-33184

**Phone**

+98 61 1373 8331

**Fax**

+98 61 1336 1544

**Email**

Industry@ajums.ac.ir, Industry333@yahoo.com

**Web page address**

www.ajums.ac.ir

**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*