

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 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 Mahdیه 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

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Iran (Islamic Republic of)

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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

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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

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

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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

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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