

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Comparison of the effectiveness of Inhalation of Aromatherapy Blend containing Lavender Essential Oil and placebo on Cesarean post operative pain relief in pregnant women

#### Protocol summary

##### Summary

Study is triple blind clinical trial comparative study of inhalation of lavender essence versus placebo on post operative pain relief in cesarean surgery. 60 women, 18-35 y/o, referred to Ahwaz Imam Khomeini Hospital operating room (May 2011- September 2012) for cesarean surgery randomly divide into 2 groups. Inclusion criteria: 18-35 years old, ASA class 1 and 2 without history of HTN, coagulation disorders, Migraine and chronic headache, olfactory problem and herbal allergy. Exclusion criteria: respiratory problem during surgery, vomiting, nausea, dissatisfaction after using Essential Oil, Allergy to herbal medicine. After starting an IV line, patients will be given 500 ml of ringer solution. Then, they will undergo spinal anesthesia with 60 mg of 5 percent lidocaine and cesarean section will be performed. When the post-operative pain starts, and 4, 8, and 12 hours after that, patients will undergo aromatherapy using lavender essence. patient's pain score is measured using VAS; then patients in the case group will be requested to breathe over a piece of cotton containing 3 drops of the 10 % lavender essence oil (provided by Kashan's Jundishapour Centre of Clinical Investigations) from a distance of 10 cm for 5 minutes, then the pain score will be measured again. If the score is > 3, 100 mg of IM Diclofenac will be prescribed. In control group the same procedures will be performed, but instead of the lavender essence, 3 drops of placebo will be used. The heart rate, blood pressure, nausea, vomiting, dizziness and satisfaction will be recorded before and after the aromatherapy according to the questionnaire. After starting an IV line, patients will be given 500 ml of ringer solution. Then, they will undergo spinal anesthesia with 60 mg of 5 percent lidocaine and cesarean section will be performed. When the post-operative pain starts, and 4, 8, and 12 hours after that, patients will undergo aromatherapy using lavender

essence. patient's pain score is measured using VAS; then patients in the case group will be requested to breathe over a piece of cotton containing 3 drops of the 10 % lavender essence oil (provided by Kashan's Jundishapour Centre of Clinical Investigations) from a distance of 10 cm for 5 minutes, then the pain score will be measured again. If the score is > 3, 100 mg of IM Diclofenac will be prescribed. In control group the same procedures will be performed, but instead of the lavender essence, 3 drops of placebo will be used. The heart rate, blood pressure, nausea, vomiting, dizziness and satisfaction will be recorded before and after the aromatherapy according to the questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201204249552N1**  
Registration date: **2012-09-16, 1391/06/26**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-09-16, 1391/06/26

##### Registrant information

##### Name

Alireza Olapour

##### Name of organization / entity

Jundushapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1336 7571

##### Email address

olapour-ar@ajums.ac.ir

## Recruitment status

**Recruitment complete**

## Funding source

Ahvaz Jundishapur University of Medical Sciences, Vice Chancellor for Research and Technology

## Expected recruitment start date

2011-05-31, 1390/03/10

## Expected recruitment end date

2012-09-20, 1391/06/30

## Actual recruitment start date

empty

## Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Comparison of the effectiveness of Inhalation of Aromatherapy Blend containing Lavender Essential Oil and placebo on Cesarean post operative pain relief in pregnant women

## Public title

The effect of Lavender Essense on Cesarean post operative pain relief

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria:18-35 years old ,ASA class 1 and 2 without history of HTN ,coagulation disorders,Migraine and chronic headache ,olfactory problem and herbal allergy. exclusion criteria: respiratory problem in surgery,vomiting ,nausea ,Unsatisfaction after using Essential Oil ,Allergy to herbal medicine.

## 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: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Triple 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

Ahvaz Jundishapur University of Medical Sciences

##### City

Ahvaz

##### Postal code

##### Approval date

2011-04-17, 1390/01/28

##### Ethics committee reference number

ETH-418

## Health conditions studied

### 1

#### Description of health condition studied

Pain

#### ICD-10 code

R 52.9

#### ICD-10 code description

pain,unspecified

## Primary outcomes

### 1

#### Description

Pain after cesarian Section

#### Timepoint

Postoperative pain

#### Method of measurement

Visual Analog Scale

## Secondary outcomes

### 1

#### Description

Postoperative pain

#### Timepoint

0,4,8,12 hours after pain

#### Method of measurement

Visual Analoge Scale

## Intervention groups

### 1

#### Description

In control group,3 drops of placebo(base of aromatherapy blend without lavender essence) on a piece of cotton will be used and the patients will be requested to breathe that from a distance of 10 cm for 5 minutes.

#### Category

Treatment - Drugs

**2**

**Description**

In case group,3 drops of the 10 % lavender essence oil on a piece of cotton will be used and the patients will be requested to breathe that from a distance of 10 cm for 5 minutes.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ahwaz Jundishapur University of Medical Sciences

**Full name of responsible person**

**Street address**

Azadegan street,Imam Khomeiny hospital

**City**

Ahwaz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Jundishapur University of Medical Sciences,Vice Chancellor for Research and Technology

**Full name of responsible person**

Mostafa Fegghi

**Street address**

Jundishapur University of Medical Sciences,Vice Chancellor for Research and Technology

**City**

Ahwaz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Jundishapur University of Medical Sciences,Vice Chancellor for Research and Technology

**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**

Ahwaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Forough Sadat Razavi

**Position**

Resident of Anesthesiology

**Other areas of specialty/work**

**Street address**

Imam Khomeiny Hospital,Azadegan street

**City**

Ahwaz

**Postal code**

6193673166

**Phone**

+98 61 1336 7571

**Fax**

**Email**

fp.razavi@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Ahwaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Alireza Olapour

**Position**

Assistant Professor

**Other areas of specialty/work**

**Street address**

Imam Khomeiny hospital,Azadegan street

**City**

Ahwaz

**Postal code**

**Phone**

+98 61 1336 7571

**Fax**

**Email**

olapour-ar@ajums.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Ahwaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Forough Sadat Razavi

**Position**

Resident of Anesthesiologu

**Other areas of specialty/work**

**Street address**

**City**

**Postal code**

**Phone**

00

**Fax**

**Email**  
**Web page address**

## **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*