Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 essense versus plasebo on post operative pain reliefe in cesarean surgery.60 women,18-35 y/o, referred to Ahwaz Imam Khomeiny Hospital operating room(May 2011- September 2012) for cesarean surgery randomly devide 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 ,unsatisfaction 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 ipatients 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 ipatients 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

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Name of organization / entity

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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
Ahwaz Jundishapur University of Medical Sciences
Street address
Ahwaz Jundishapur University of Medical Sciences
City
Ahwaz
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 essense) 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 essense 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 Scienses
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 Feghhi
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
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Full name of responsible person
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Person responsible for updating data

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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