Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the Effect of Aromatherapy on Pregnant mothers with Flavors of Citrus aurantium on the Apgar score of newborn infants during elective cesarean section surgery

Protocol summary

Study aim

Investigating the Effect of Aromatherapy on Pregnant mothers with Flowers of Citrus aurantium on the Apgar score of newborn infants during elective cesarean section surgery

Design

This is a double-blind randomized study. The study group consisted of 92 women referred to Jahrom Motahhari Hospital who underwent cesarean section.

Settings and conduct

The study will be carried out at Motahari Hospital in Jahrom. The person is asked to inhale essential oil for 30 minutes and this process will continue until entering the operating room. Then after the baby is born, Weight and apgar score will be recorded at one and five minutes after birth by a pre-trained researcher who has no knowledge of whether the patient and her infant are in the intervention or control group and Similarly, these steps perform using three drops of distilled water in the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria included pregnant mothers' consent to participate in the study; 18-35 years of age; no sensitivity to spring orange; term pregnancy; no analgesic use in the past 8 hours and no respiratory disease.Exclusion criteria included patient dissatisfaction and respiratory problems during surgery.

Intervention groups

Half an hour before entering the operating room, the aromatherapy mixture containing 3 drops of 10% Citrus aurantium , prepared by Tebab Drug Company, is poured onto a cotton pad and we ask the person to breathe for 10 minutes from a distance of 10 cm(the essential oil cotton is attached to the collar of patients' operating room 10 cm from the nose) and this process will continue until entering the operating room. Then after the baby is born, her/his apgar score will be measured by the researcher at one and five minutes after birth.

Main outcome variables

Apgar score in infants one and five minutes after birth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130718014049N10**
Registration date: **2020-04-12, 1399/01/24**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-12, 1399/01/24**
Update count: **0**

Registration date

2020-04-12, 1399/01/24

Registrant information

Name

Ali Abbasi Jahromi

Name of organization / entity

Jahrom University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-29, 1399/01/10

Expected recruitment end date

2020-06-30, 1399/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Aromatherapy on Pregnant mothers with Flavors of Citrus aurantium on the Apgar score of newborn infants during elective cesarean section surgery

Public title

The effect of aromatherapy in women undergoing cesarean section with spinal anesthesia on neonatal apgar score

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All patients undergoing cesarean section at Motahari Hospital of Jahrom University of Medical Sciences. Spinal anesthesia for the mother has been approved by the anesthesiologist. Term pregnancy Patient Satisfaction to Participate in the Study and No Sensitivity to Citrus aurantium Term pregnancy Non-emergency surgery

Exclusion criteria:

Respiratory Disease Pain medication for the past 8 hours Incidence of labor complications such as vaginal bleeding during research Addiction and psychotropic drugs The patient and his wife declare their consent to continue the study

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize the subjects, the dice will be divided into two groups: intervention and control.In this way, once a dice is thrown for each patient, the patient with will be in the even number will be in intervention group, and patient with odd number will be in the control group.In addition the person evaluating the consequence is unaware of the manner and results of this accident.

Blinding (investigator's opinion)

Double blinded

Blinding description

A double blind method was used for blinding in this study so that 1- volunteer 2- Neonatal Apgar Scale Measurer does not know about intervention and control groups.Both intervention and control groups will be told that drops of liquid will be poured onto the cotton and you will be asked to breathe in with normal breathing;So they won't know the type of drop.Due to the fact that the patient of the intervention group did not know the type of substance used in the patient, the control group (distilled water) and while our dependent variable is measured from the newborn،Therefore, the mother and baby do not know their intervention group،So if the mother's condition affects the dependent variable, which is measured from the baby, the mother still has no knowledge of her intervention or control group.،Because it does not know the type of material used in the control group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Jahrom University of Medical Sciences

Street address

Ethic committee, Jahrom University of medical science, martyr Motaharie Blvd, Jahrom

City

Jahrom

Province

Fars

Postal code

4619974148

Approval date

2020-02-25, 1398/12/06

Ethics committee reference number

IR.JUMS.REC.1398.096

Health conditions studied

1

Description of health condition studied

Apgar score scale after maternal aromatherapy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Apgar score
Timepoint
The first minute after birth
Method of measurement
Based on Apgar Scale

2

Description
Apgar score
Timepoint
Fifth minute after birth
Method of measurement
Based on Apgar Scale

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Half an hour before entering the operating room, 3 drops of distilled water are poured on a cotton pad and we ask the person to breathe for 10 minutes from a distance of 10 cm (cotton soaked in distilled water). It is attached to the collar of the patient's operating room collar (10 cm from the nose) and will continue until the operating room arrives. Then after the baby is born, Weight and apgar score will be recorded at one and five minutes after birth by a pre-trained researcher who has no knowledge of whether the patient and her infant are in the intervention or control group.
Category
N/A

2

Description
Intervention group: Half an hour before entering the operating room, the aromatherapy mixture containing 3 drops of 10% Citrus aurantium , prepared by Tebab Drug Company, is poured onto a cotton pad and the person is asked to rest for 30 minutes on a regular basis. Breathe in with a normal breath of 10 cm (the essential oil cotton is attached to the collar of patients' operating room 10 cm from the nose) and this process will continue until entering the operating room. Then after the baby is born, Weight and apgar score will be recorded at one and five minutes after birth by a pre-trained researcher who has no knowledge of whether the patient and her infant are in the intervention or control group.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
En Jahrom 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
IPD collected for the primary outcome measure only
When the data will become available and for how long
Six months after the results were published
To whom data/document is available
Only available for people working in academic institutions
Under which criteria data/document could be used
Only scientific and practical use is permitted
From where data/document is obtainable
Jahrom university of medical sciences
What processes are involved for a request to access data/document
Apply to university and receive information
Comments