Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical trial of Comparison The effect of aromatherapy with essential oil of Rosa damascene and lavender in the single and mixed from on pain, anxiety and duration of first and second stages of labor in primigravida women.

Protocol summary

Summary

This study is a randomized blind clinical trial study to compare the effect of aromatherapy with essential oil of rosa damascena and lavender in the single and mixed form on pain intensity, anxiety level and used during the first and second stages of Labour in primigravida women. The study population consisted of all pregnant women who were admitted to delivery wards in Zahedan. 120 pregnant women eligible for the study sample were selected and then the draw up and randomly selected the units in to four groups (inhalation of rose, lavender, combining rose and lavender and inhalation of distilled water.) and 30 patients were in each group. The day when the patients were studied the pain intensity using the Visual Analogue Scale (VAS) was reviewed. Then poured oil on the gaute and clipped to the women collars and were asked to inhale their fragrance during uteral contractions . Again pain intensity was measured 30 and 60 minutes after the beginning of the study. In the control group distilled water was used instead of oil, and the intensity of pain was studied in other groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012323370N4**
Registration date: **2017-04-23, 1396/02/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-04-23, 1396/02/03

Registrant information

Name
Maryam Navaee
Name of organization / entity
Nursing and Midwifery Faculty
Country
Iran (Islamic Republic of)
Phone
+98 54 3344 4510
Email address
navaee.m@zamuc.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of Comparison The effect of aromatherapy with essential oil of Rosa damascene and lavender in the single and mixed from on pain, anxiety and duration of first and second stages of labor in primigravida women.

Public title

effect of aromatherapy on pain, anxiety and duration of first and second stages of labor

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criterias:Age between 18-35; Normal pregnancy between 42-38 weeks; Cephalic presentation; Normal fetus and amniotic fluid index; Singleton pregnancy; Dilatation of the cervix 3-4 cm, At least the fifth class of the primary education and no history of infertility;The absence of acute and chronic diseases; Asthma, eczema and allergies; Lack of anxiety and known depression diseases; Not taking anti-anxiety drugs; No addiction to narcotic drugs; Since last six months had no severe emotional disorders; And they shouldn't be from the medical staff. Exclusion criterias: Receiving analgesics; Sedatives and narcotics drugs with in three hours of the beginning and during the study; Use of oxytocin for induction and augmentation of Labour; All mothers who were discharged the natural course of Labour and were in need of intensive care or emergency cesarean section, Or had allergy to the used material.

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: **120**

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
Vice chancellor for research, Zahedan University of Medical Sciences

Street address
Zahedan University of Medical Sciences, Khalije Fars Boulevard, Zahedan, Ira

City
Zahedan

Postal code
98167-43463

Approval date
2014-07-13, 1393/04/22

Ethics committee reference number
ir.zaums.rec.1393.6733

Health conditions studied

1

Description of health condition studied
pain and anxiety and duration of first and second stages of labor

ICD-10 code
O60-75

ICD-10 code description
Complications of labour and delivery

Primary outcomes

1

Description
Anxiety

Timepoint
At the beginning of the active phase and before the intervention and again after giving birth

Method of measurement
With anxiety inventory Spillberger

2

Description
Pain

Timepoint
30 and 60 minutes after intervention

Method of measurement
Using a numerical pain scale (VAS)

3

Description
First stages of labor

Timepoint
Once and from the beginning to the end of the active phase

Method of measurement
using a researcher-made questionnaire

4

Description
Second stages of labor

Timepoint
Once and from the beginning to the end of the active phase

Method of measurement
Using a researcher-made questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
On the nulliparous women with VAS pain intensity and anxiety level were assessed by questionnaire "Eshpel Burger" into four groups and then intervention was divided into three groups as below. The first group inhaled 0.1 ml rose mixed with 2 ml of distilled water, the second group inhaled 0.1 ml of lavender oil mixed with 2 ml of distilled water, the third group inhaled 0.1 ml Rose and 0.1 ml of lavender oil mixed with 2 ml of distilled water. Then poured oil on the guate and clipped to the collars of the women and asked them to inhale their fragrance during uteral contractions. Pain intensity and anxiety level were measured again 30 and 60 minutes after the intervention. The duration of the first stage and second stage were measured and recorded by the researcher.

Category
Placebo

2

Description
In the control group ,placebo or normal saline (N/S) was used in the place of oil so that in the active phase of the Labour two drops of saline is poured on the threaded guates. pain intensity is measured by VAS and the anxiety level by questionnaire "Eshpel Burger" 30 and 60 minutes after intervention was measured. The duration of the first and second stage were measured and recorded by the researcher.

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Ali Hospital
Full name of responsible person
Parvaneh Pahlavan
Street address
Khalije Fars Boulevard, Zahedan, Iran
City
Zahedan

2

Recruitment center
Name of recruitment center
Nabiakram Hospital
Full name of responsible person
Tahereh Rajaee
Street address
Motahari Boulevard, Zahedan, Iran
City
Zahedan

3

Recruitment center
Name of recruitment center
Taamin Ejtemaee Hospital
Full name of responsible person
Zahra Saravani
Street address
Parastar Square, Zahedan, Iran
City
Zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Zahedan University of Medical Sciences
Full name of responsible person
Dr. Mohsen Taheri
Street address
Zahedan University of Medical Sciences, Khhalije fars Square, Zahedan,Iran
City
Zahedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Zahedan 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
Faculty of Nursing and Midwifery
Full name of responsible person
Maryam Navaee
Position
Master degree, faculty member
Other areas of specialty/work
Street address
Behdasht Street, Zahedan, Iran
City
Zahedan
Postal code

Phone
+98 54 3344 4510
Fax
Email
helennavaee@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Faculty of Nursing and Midwifery
Full name of responsible person
Maryam Navaee
Position
Master degree, faculty member
Other areas of specialty/work
Street address
Behdasht Street, Zahedan, Iran
City
Zahedan
Postal code
Phone
+98 54 3344 4510
Fax
Email
helennavaee@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Faculty of Nursing and Midwifery
Full name of responsible person
Maryam Navaee
Position
Master degree, faculty member
Other areas of specialty/work
Street address
Behdasht Street, Zahedan, Iran
City
Zahedan
Postal code
Phone
+98 54 3344 4510
Fax
Email
helennavaee@gmail.com
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