Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the efficacy of lavender aroma and valerian in reducing labor pain and Progress of labor in nulliparous women

Protocol summary

Summary

The aim of this double blind randomized trial, is evaluation of the effects of Lavender aroma and Valerian in reducing labor pain and progress of labor in nulliparous women in Hazrate Fateme hospital in Miandoab. Enrolled mothers will be randomly allocated into 3 groups (Lavender, Valerian or placebo) using block randomization method. Lavender, Valerian and a placebo oils with similar glasses and appearance will be prepared by Bareej Essence Pharmacotical Company. The aromatic substance will be impregnated by the researcher assistant and the packets will be prepared. Participants will enter to the study in order number written on each envelope. Labor pain intensity will be evaluated using Visual Analogue Scale when cervix dilatation is 4 cm in 3 groups. Then researcher opens the corresponding subject envelope and places drops from Glass labeled 1, 2 or 3 on a cotton ball and the patient will smell it for 10 minutes every one hour. The amniotic fluid, duration of rupture of membranes, liquid paints, fetal heart rate, medications, cervical dilatation and fetal descent rate, number and duration of contractions, the baby's Apgar score at one and five minutes of observation and examination will be recorded. The Pain also will be measured by Visual Analog Scale in dilatations 6, 8, 9 and 10 centimeter.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504236582N10**
Registration date: **2015-05-30, 1394/03/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-05-30, 1394/03/09

Registrant information

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Mahin Kamalifard
Name of organization / entity
Tabriz University of Medical Sciences and Health Services
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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the efficacy of lavender aroma and valerian in reducing labor pain and Progress of labor in nulliparous women

Public title

Comparison the efficacy of lavender aroma and valerian in reducing labor pain and Progress of labor in nulliparous women

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion Criteria: Primiparous pregnancy; age 18-35; gestational age of 37-41 w; singleton fetus; active phase; cephalic presentation; no smoking; no addiction; no Lack of vision; no history of chronic heart diseases, lung diseases, according to the patient's expression; the absence of eclampsia; and placenta previa; no PROM for more than 18 hours; no history of infertility; willingness to participate in the study; no history of sensitivity; the presence of low-risk pregnancies. Exclusion Criteria: Get analgesic medication during the 3 hours before the start of the study; systolic blood pressure less than 95 mm Hg.

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: **141**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences

Street address
Central Building No. 2, Research Administration,Tabriz University of Medical Sciences, Daneshgah st.

City
Tabriz

Postal code

Approval date
2015-03-09, 1393/12/18

Ethics committee reference number
93192

Health conditions studied

1

Description of health condition studied
Labor pain

ICD-10 code
O83.8

ICD-10 code description
Other specified assisted single delivery

Primary outcomes

1

Description
intensity of labor pain

Timepoint
before intervention, 6-8-10cm of cervix dilatasion

Method of measurement
VAS (Visual Analog Scale)

Secondary outcomes

1

Description
The duration of the active phase

Timepoint
each 2 hour

Method of measurement
vaginal examination

2

Description
Duration of the second stage of labor

Timepoint
from full dilatasion until lTime of Birth

Method of measurement
Questionnaire

3

Description
Neonatal outcomes (The first and fifth minute Apgar scores and Refer to the NICU)

Timepoint
After birth

Method of measurement
Questionnaire

4

Description
Type of delivery

Timepoint
After birth

Method of measurement
Questionnaire

5

Description
Side effects (Nausea and vomiting)

Timepoint
During the study
Method of measurement
cheklist

Intervention groups

1

Description
In Lavender group in dilatations 4 ;every hour, 3 drops of lavender aroma (Glass labeled 1) Drops on a cotton ball and the patient will be close to their nose and smell it for 10 minutes.
Category
Treatment - Drugs

2

Description
In valerian group in dilatations 4 cm; every hour, 3 drops of valerian aroma (Glass labeled 2) Drops on a cotton ball and the patient will be close to their nose and smell it for 10 minutes of every hour.
Category
Treatment - Drugs

3

Description
In Olive oil group in dilatations 4; every hour, 3 drops of Olive oil aroma (Glass labeled 3) Drops on a cotton ball and the patient will be close to their nose and smell it for 10 minutes.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Fatemeh Hospital
Full name of responsible person
Rana Dosty
Street address
Hazrat Fatemeh Hospital,Saheli St, Miandoab, East Azarbayjan.
City
Miandoab

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mahin Kamalifard
Street address
Nursing and Midwifery, South Shariati Ave.
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Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
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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