

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

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

Protocol summary

2015-05-30, 1394/03/09

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

Registrant information

Name

Mahin Kamalifard

Name of organization / entity

Tabriz University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

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Email address

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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 dilatation

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 dilatation until Time 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

checklist

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****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mahin Kamalifard

Position

Senior lecturer, Academician

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Nursing and Midwifery, Tabriz University of Medical Sciences

Full name of responsible person

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Position

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Full name of responsible person

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Postal code**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