

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of essential oil of lavender on duration of pregnancy in primigravida women with late preterm labor

Protocol summary

Summary

Objective: to determine the effect of lavender essential oil on the length of gestation in nulliparous women with late preterm labor. Design: clinical trial that is triple-blind, three-group and multicenter. Researcher at first after taking confirmation of the university ethics committee and provide a referral to hospital officials Imam Reza, Ghaem and Omolbanin (Mashhad, Iran), and permission to enter the gynecology ward. Samplers of primiparous women who were admitted with a diagnosis of late preterm delivery by inhibiting contractions that are ready to be discharged from the hospital, have the desire to participate in the study and the conditions of entry will be done. Since would be first pilot study, Since would be first pilot study, 30 cases in the intervention group and the control group with the placebo and control group without the intervention will be studied. For all groups, demographic questionnaire and pregnancy and recording of patient records and Spielberg questionnaire will be completed. Almond oil and lavender oil was used as placebo and medicine respectively. Pure essential oils of lavender product by Barij Essence(Kashan, Iran) that is diluted by pharmacist with 1 in 9 ml almond oil. The use of the drug in the abdomen and the 3 drops and three times a day. The researcher will teach women how to use. During the study, information daily by women will be collected by a questionnaire. During the study, researchers will follow up women twice a week. The data will be examined spss software. Inclusion criteria: first pregnant women; living in Mashhad city; gestational age based on ultrasound of the first quarter or the first day of the last menstrual period the first quarter 34- 36 weeks and 6 days; late preterm labor diagnosis; tend to participate in the study; aged between 18 and 35 years old; no specific illness; healthy amnion sac; no fever tend to be Iranian; have literacy; have singleton pregnancy; not having fetal distress; not having a ban on the use of aromatherapy, such as asthma, allergies; not having abnormalities of the uterus and fetus on ultrasound

during pregnancy; not having a horrible event the last 6 months. Exclusion criteria during the study: sensitivity to be lavender essential oil; unwillingness to continue taking the drug by patients who are complications such as severe disability, or at least a continuous weeks or more than 3 days of medication per week; have fever(oral temp $\geq 38^{\circ}\text{C}$). Sample size in the final will be 60 cases.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051422280N1**

Registration date: **2015-09-15, 1394/06/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-15, 1394/06/24

Registrant information

Name

Zainab Bolghanabadi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 4222 4823

Email address

bolghanabadiz911@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-04-20, 1394/01/31
Expected recruitment end date
 2015-11-21, 1394/08/30
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Effect of essential oil of lavender on duration of pregnancy in primigravida women with late preterm labor

Public title
 Effect of essential oil of lavender on duration of pregnancy in primigravida women with late preterm labor

Purpose
 Prevention

Inclusion/Exclusion criteria
 Inclusion criteria: first pregnancy; living in Mashhad city, Iran; gestational age based on the first day of the last menstrual period or by Sonography be 34 – 36.6 weeks; diagnosis of late preterm labor; the desire to participate in the study have; age between 18 to 35 years old; no specific disease; normal amniotic sac; no fever (Temperature $\geq 38^{\circ}\text{C}$); have Iranian nationality; have literacy; singleton pregnancy; no fetal distress; no contraindications for aromatherapy such as asthma; during the last 6 months have been a horrible accident; no embryonic and fetal anomalies by ultrasound during pregnancy. Exclusion criteria: allergic to lavender essential oil; accidents happen during research; unwillingness to continue taking the drug by patients; complications such as severe disability, or at least a continuous weeks or more than 3 days of medication per week; have fever(oral temp $\geq 38^{\circ}\text{C}$).

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

Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Shahid Fakouri Boulevard, between Shahid Javan and Shahid Al-Shahidi

City

Mashhad

Postal code

9177899191

Approval date

2015-05-14, 1394/02/24

Ethics committee reference number

research/931022/1/465

Health conditions studied

1

Description of health condition studied

Pereterm labor

ICD-10 code

O60.0

ICD-10 code description

Onset (spontaneous) of labour before 37 completed weeks of gestation

Primary outcomes

1

Description

Length of pregnancy

Timepoint

After intervention until delivery

Method of measurement

Medical records

Secondary outcomes

1

Description

Anxiety

Timepoint

Before the intervention, and every day after intervention

Method of measurement

Visual analgous Scale

Intervention groups

1

Description

Control 1: sweet almond oil place the abdominal locally to 3 drops 3 times a day

Category

Placebo

2

Description

Intervention group: lavender essential oil diluted 1: 9 in
Place of intervention: abdominal locally to 3 drops 3 times a day

Category

Treatment - Drugs

3

Description

Control 2: without intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ommol Banin Hospital

Full name of responsible person

Tara, Fatemeh

Street address

Ayatollah Behjat Avenue, Ayatollah Behjat 16th

City

Mashhad

2

Recruitment center

Name of recruitment center

Emam Reza Educational, Research and Treatment Center

Full name of responsible person

Street address

Emam Reza Hospital, Emam Reza Square, Ebne Sina Avenue

City

Mashhad

3

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Nafise Saghafi

Street address

Ghaem Educational, Research and Treatment Centerbeginning of Ahmadabad Avenue

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Vice chancellor for research, Mashhad University of Medical Sciences, Daneshgah St.

City

Mashhad

Grant name

بودجه معاونت پژوهش و فناوری

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

School of Nursing and Midwifery, Mashhad University of Medical Sciences

Full name of responsible person

Zeinab Bolghanabadi

Position

Bachelor of Midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Firoozi, Mahboube

Position

Master degree

Other areas of specialty/work**Street address**

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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

Person responsible for updating data

Contact

Name of organization / entity

School of Nursing and Midwifery, Mashhad University of Medical Sciences

Full name of responsible person

Zeinab Bolghanabadi