

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect aromatherapy with lavender on sleep quality third trimester pregnant women

Protocol summary

Summary

Objective: This study is designed aimed to determine the effects of lavender aromatherapy on sleep quality in pregnant women in the third trimester. This study is an intervention study and design for the two groups (exam and control group) with two per-test and post-test. Community formation pregnant women referred to the center of physiologic delivery Fatemieh hospital in Hamadan .A sample of 36 patients in the intervention group and 36 patients in the control group has been set. After completing the Pittsburgh questionnaire via primary pregnant women who have entered the third trimester (from week 29 of pregnancy) and Determine People who have score high 5 on the questionnaire Pittsburgh and Inclusion criteria are having, 72 people randomly placed into two groups: control and test. Mothers in the intervention group to be delivered Lavender essential oil produced from Barij Esanse. For a month, four days a week at night before going to bed two drops of the contents of the glass on a clean cloth or cotton fabric and With a distance of 20 cm from the nose, 10 deep breath and beside your pillow until the morning. In weeks 2 and 4 after intervention by individuals in the experimental group and Control group completed questionnaires Pittsburgh .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061710426N11**
Registration date: **2016-06-28, 1395/04/08**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-06-28, 1395/04/08

Registrant information

Name

Parisa Parsa

Name of organization / entity

Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2016-07-01, 1395/04/11

Expected recruitment end date

2017-07-01, 1396/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect aromatherapy with lavender on sleep quality third trimester pregnant women

Public title

The effect aromatherapy with lavender on sleep quality third trimester pregnant women referred to Fatemieh hospital in Hamadan in 2016

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age ranged between 18-35 years; primi- gravid; lack of lavender mother's insensitivity; lack of physical and mental illness in the mother; lack of

stress and domestic violence against the mother; the absence of high-risk pregnancy symptoms in the mother; No history of allergic rhinitis; eczema or breathing problems such as asthma ;lack of drug addiction. Exclusion criteria:The incidence of allergy symptoms in the mother, lavender inhaled less than four times a week.

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: **72**

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

Ethics committee of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences- Shahid Fahmideh Street- Counterpoint of Mardom Park- Hamadan

City

Hamadan

Postal code

65178

Approval date

2016-04-23, 1395/02/04

Ethics committee reference number

IR.UMSHA.REC.1395.33

Health conditions studied

1

Description of health condition studied

Aromatherapy with lavender on sleep quality in pregnancy; Pregnancy-related condition, unspecified

ICD-10 code

O26.9

ICD-10 code description

Pregnancy-related condition, unspecified

Primary outcomes

1

Description

sleep quality

Timepoint

before, two weeks after intervention-four weeks after intervention

Method of measurement

Standard Pittsburgh Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: After obtaining written testimonial from samples, People who score high of 5 in the questionnaire, Coincidentally divided with the lottery with a coin into one of two groups of experimental group and the control group. Mothers in the intervention group to be delivered Lavender essential oil produced from Barij Esanse. Mothers will ask for a a month, four days a week at night before going to bed two drops of the placebo contents put in a clean cloth or cotton fabric and inhale it with a distance of 20 cm from their nose. After 10 deep breath, put it beside pillow until the morning. After 2 and 4 weeks control group will complete the Pittsburgh questionnaires .

Category

Treatment - Drugs

2

Description

Control : . Mothers in the control group to be delivered placebo (water) in a bottle as same as intervention group.Mothers will ask for a a month, four days a week at night before going to bed two drops of the placebo contents put in a clean cloth or cotton fabric and inhale it with a distance of 20 cm from their nose. After 10 deep breath, put it beside pillow until the morning. After 2 and 4 weeks control group will complete the Pittsburgh questionnaires .

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemih Hospital

Full name of responsible person

Fahimeh Ezati Arasteh

Street address

Shahid Zamani, Fatemih Hospital

City

Hamadan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamadan University of Medical Sciences

Full name of responsible person

Dr. Saied Bashirian

Street addressShahid Fahmideh Street, Counterpoint of Mardom
ParkHamadan University of Medical Sciences**City**

Hamadan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamadan 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**

Hamadan University of Medical Sciences

Full name of responsible person

Dr. Parisa Parsa

Position

Associate Professor

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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