Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Pittsburg .

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
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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 address
Shahid 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
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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