Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effects of inhalation aromatherapy with rose and lavender and odorless sesame seed oil and Musk willow on postpartum depression in women at risk: a clinical trial

Protocol summary

Summary

This study aims to examine the effect of aromatherapy with damask rose & lavender on postpartum depression in women at risk. This research is a double-blind clinical trial conducted on 105 pregnant women in 35th -37th week of pregnancy who will attend two health care center, affiliated to Yazd University of Medical Sciences. After getting informed consent from pregnant women who meets the inclusion criteria, HADS and Edinburgh questionnaire will be completed and pregnant women will be excluded from the study if they give score 13 and above from Edinburg questionnaire score 11 or above from each component of HADS questionnaire. Pregnant women will randomly be categorize into three groups of intervention and control. The intervention is Intervention group: inhaling 7 drops of lavender essential oil with 1 cc of Rosewater with a concentration of 100%, produced by the Barij Company, 10 times before sleeping, from 38th week of gestational age until six weeks after delivery. In placebo group this process will be followed: inhaling 7 drops of sesame seed oil with 1 cc of Musk willow with a concentration of 100%, produced by the Barij Company, 10 times before sleeping, from 38th week of gestational age until six weeks after delivery. Control group will receive routine care. Then 2 and 6 weeks after delivery , the degree of depression will be measured by Edinberg scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080929281N1**
Registration date: **2017-01-03, 1395/10/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-01-03, 1395/10/14

Registrant information

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Fateme Moshirenia
Name of organization / entity
Isfahan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Isfahan University of Medical Sciences

Expected recruitment start date

2015-06-20, 1394/03/30

Expected recruitment end date

2016-04-18, 1395/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of inhalation aromatherapy with rose and lavender and odorless sesame seed oil and Musk willow on postpartum depression in women at risk: a clinical trial

Public title

The effect of aromatherapy on postpartum depression

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: being literate; having Iranian nationality; No abnormalities in infant According to Ultrasound exam; no drugs or alcohol consumption by the mother; mother not being affected by known chronic or systemic diseases; no consumption of anti depressant or anti anxiety medications in recent pregnancy; no history of asthma, allergy, or dermatitis diagnosed by a physician; no history of eczema and allergy to flowers and plants diagnosed by a physician; Not having perceived social support from the side of family and friends for current pregnancy; Unwanted pregnancy; Unemployed husband; having Stressful life events in the last 12 months before delivery Exclusion criteria: allergy to lavender and rose essential in the subjects or their family members.

Age
No age limit

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
The three groups before and after the three-step test plan

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Azadi Sq, Hezar Garib Ave, Isfahan, Iran

City
Isfahan

Postal code
8174673461

Approval date
2013-12-16, 1392/09/25

Ethics committee reference number
394408

Health conditions studied

1

Description of health condition studied
Postpartum Depression

ICD-10 code
F53.0

ICD-10 code description
Mild mental and behavioural disorders associated with the puerperium, not elsewhere classified

Primary outcomes

1

Description
Postpartum Depression.

Timepoint
Before the intervention, two weeks after giving birth and six week.ks after giving birth

Method of measurement
Edinburgh questionnaire.

Secondary outcomes

1

Description
_

Timepoint
_

Method of measurement
_

Intervention groups

1

Description
Intervention group: inhaling 7 drops of lavender essential oil with 1 cc of Rosewater with a concentration of 100%, produced by the Barij Company, 10 times before sleeping, from 38th week of gestational age until six weeks after delivery

Category
Treatment - Drugs

2

Description
Placebo group: inhaling 7 drops of sesame seed oil with 1 cc of Musk willow with a concentration of 100%, produced by the Barij Company, 10 times before sleeping, from 38th week of gestational age until six weeks after delivery

Category
Treatment - Drugs

3

Description
Control group: they receive routine care.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mirjalily Center
Full name of responsible person
Miss Rangbar
Street address
Health Center of Shahid Mirjalili, Anar Sq, Shohadah Ave, Shahediyah, Yazd, Iran
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2

Recruitment center
Name of recruitment center
Taleghany Center
Full name of responsible person
Miss Asayesh
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Health Center of Shahid Taleghani, Basig Sq, Maglesi Ave, Zarg, Yazd, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Isfahan University of Medical Sciences
Full name of responsible person
Maryam kianpour
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Esfahan University of Medical Sciences, Azadi Sq, Hezar Garib Ave, Isfahan, Iran
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Esfahan
Grant name
Grant code / Reference number
_
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research,Isfahan 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