

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 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

Name

Fateme Moshirenia

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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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 weeks 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 centers1**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 sources1**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

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****Name of organization / entity**

Isfahan University of Medical Sciences

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Position

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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