Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effectiveness of aromatherapy with Rosa damascena Mill. to relieve the symptoms of postpartum depression in primiparous women

Protocol summary

Study aim
Determining the effectiveness of aroma therapy with rose (Rosa damascena Mill.) on relieving postpartum depression symptoms in nulliparous women

Design
A clinical trial with a control group, with parallel, non-blind, randomized phase 3 groups on 60 patients, used block method and quadruple blocks for randomization.

Settings and conduct
This clinical trial will be performed by easy sampling method on 60 nulliparous women admitted to the postpartum ward of hospitals under the auspices of Babol University of Medical Sciences. During the first 24 hours after delivery and after the mother has stabilized and obtained written consent and completed the questionnaires, the samples will be divided into two groups of 30 people A and B. Group A or intervention group includes patients receiving rose essential oil and group B or comparison group includes patients receiving base oil as a placebo. According to the type of intervention, only the primary and secondary outcome assessor is unaware of the type of intervention, and also the data is provided to the statistical expert for statistical analysis in a blind and randomized code.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Be literate، age 20-35 years، do not use Drugs and Alcohol، no history of Asthma, Allergies or skin Dermatitis diagnosed، lack of known mental disorders، get a score below 13 according to the Edinburgh Depression Inventory and the birth of a seemingly healthy baby Exclusion criteria: Sensitivity to the oils provided، history of sensitivity to special oils in one of the family members of the subjects

Intervention groups
Group A or intervention group includes patients receiving rose essential oil and group B or comparison group includes patients receiving base oil as a placebo.

Main outcome variables
Depression score in the Edinburgh postpartum depression questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180218038783N1**
Registration date: **2020-11-08, 1399/08/18**
Registration timing: **prospective**

Last update: **2020-11-08, 1399/08/18**
Update count: **0**

Registration date
2020-11-08, 1399/08/18

Registrant information

Name
Fereshteh Behmanesh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-07, 1399/09/17

Expected recruitment end date
2022-01-07, 1400/10/17

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of aromatherapy with Rosa damascena Mill. to relieve the symptoms of postpartum depression in primiparous women

Public title
"Effectiveness of Aromatherapy with Rosa damascena Mill. in treatment of postpartum depression"
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Be literate Age 20-35 years Do not use Drugs and Alcohol No history of Asthma, Allergies or skin Dermatitis diagnosed No history of Allergies and Eczema diagnosed to flowers and plants Lack of known mental disorders Do not use Anti-stress and Anti-depressant drugs Having a sense of smell Get a score below 13 according to the Edinburgh Depression Inventory The birth of a seemingly healthy baby
Exclusion criteria:
Sensitivity to the oils provided History of sensitivity to special oils in one of the family members of the subjects
Age
From **20 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible individuals are randomly divided into four groups (permuted block randomization) and open lable in one of two treatment groups A with a size of 30 and B with a size of 30. The size of the blocks is 4 and in each block, each intervention group will be repeated twice. 15 blocks of 4 will be produced 15 times to create a total of 60 sequences. Group A or intervention group includes patients receiving rose essential oil and group B or comparison group includes patients receiving base oil as a placebo. To hide the random allocation list, a special code will be assigned to each of the intervention groups that only the principal executor (supervisor) is aware of. These codes are written on a piece of paper and placed in a sealed envelope. A single code specific to each patient will be written on this paper as well as on the envelope. All envelopes are placed in a larger box in random order and will be sealed in the box. The evaluator will not know about the allocation of two groups of rose essential oil and placebo. Blinding: According to the type of intervention, only the primary and secondary outcome assessor is unaware of the type of intervention, and also the data is provided to the statistical expert for statistical analysis in a blind and randomized code.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Babol University of Medical Sciences
Street address
Keshavarz- Babol University Of Medical Sciences
City
Babol
Province
Mazandaran
Postal code
4717647745
Approval date
2020-04-21, 1399/02/02
Ethics committee reference number
IR.MUBABOL.REC.1399.096

Health conditions studied

1

Description of health condition studied
Postpartum Depression
ICD-10 code
000
ICD-10 code description
Service Temporarily Down

Primary outcomes

1

Description
Depression score in the Edinburgh postpartum depression questionnaire
Timepoint
Determination of depression score in the first 24 hours after delivery (before intervention), 6 weeks and 12 weeks after starting rose essential oil.
Method of measurement
Edinburgh Postpartum Depression questionnaire

Secondary outcomes

1

Description
Sleep quality score
Timepoint
Determining the quality of sleep in the first 24 hours after delivery (before the intervention), 6 weeks and 12 weeks after starting rose essential oil
Method of measurement
pittsburgh sleep quality index

Intervention groups

1

Description
Intervention group: Mothers who, after discharge, put a cc of rose essential oil on a special cloth and put it on their mouth and nose every night before going to bed for 12 weeks after giving birth, using a dropper, and take 10 deep breaths, and then They put the cloth next to their pillow until morning.
Category
Treatment - Drugs

2

Description
Control group: Mothers who, after discharge, put a cc of distilled water on a special cloth and put it on their mouth and nose every night before going to bed for 12 weeks after giving birth, using a dropper, and take 10 deep breaths, and then They put the cloth next to their pillow until morning.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Postpartum wards of hospitals under the auspices of Babol University of Medical Sciences
Full name of responsible person
Fereshteh Behmanesh
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Sponsors / Funding sources

1

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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Fereshteh Behmanesh
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Evaluation of the effectiveness of aromatherapy with Rosa damascena Mill. to relieve the symptoms of postpartum depression in primiparus women
When the data will become available and for how long
7 December 2021
To whom data/document is available
Babol University of Medical Sciences research deputy
Under which criteria data/document could be used
Postpartum Depression
From where data/document is obtainable
Postpartum ward of hospitals under the auspices of Babol University of Medical Sciences
What processes are involved for a request to access data/document
Request of the Deputy of Health Research Institute of Babol University of Medical Sciences
Comments