

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Aug 2026

Comparison the effect of Lavender and Mint oil on nausea, vomiting and anxiety in pregnant women

Protocol summary

Summary

Objectives: The aim of this study is comparison of the effect of aromatherapy Lavender and Peppermint on nausea, vomiting and anxiety in pregnant women.

Design: This randomized clinical trial; single-center; placebo-controlled included 99 pregnant women who will be referred to the prenatal care clinic. Participants randomly will be allocated into 2 interventions and a control group (placebo). Inclusion criteria: Pregnant women in 6 to 16 weeks of gestational age with a mild to moderate nausea and vomiting; single pregnancy with an alive and healthy fetus according to the Ultrasound. Exclusion criteria: not to have any tendency to continue participating in the study; severe nausea and vomiting that needs to use drugs. Researcher explains routine cares to participants. Participants in two intervention groups will be dropped Lavender or Peppermint oil (made by Barij Company) on a piece of cotton pad and will attach to their dress collar within 20 cm distance from nose and they will breathe normally for 20 minutes. This process continues 2 times a day for 1week. The control group does the same process with placebo instead. Main outcome: nausea, vomiting and anxiety. Rhodes index questionnaire that include 8 questions will be given to all participants to be complete before bedtime. Also by STAIT anxiety questionnaire will be completed by the research assistant before and at the end of the interventions. The scores will be calculate and compared together.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306082324N12**

Registration date: **2014-09-23, 1393/07/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-09-23, 1393/07/01

Registrant information

Name

Maryam Keshavarz

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2014-06-05, 1393/03/15

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Lavender and Mint oil on nausea, vomiting and anxiety in pregnant women

Public title

Comparison the effect of Lavender and Mint oil on nausea, vomiting and anxiety in pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Gestational age 6-16 weeks based on LMP or Ultrasound; Age 15-34 year ; Having mild to moderate nausea and vomiting (based on Rhodes index); Ashpylberger Anxiety Scale scores will obtained from less than 53 in state anxiety; Single pregnancy with an alive and healthy fetus based on ultrasound; Ability to read and write; No olfactory disorder (according to pregnant women reporting); Not having physical, mental and emotional diseases; Lack of stressful events during the past 6 months; Not to have any allergy to herbal drugs; Not using anti emetic or emetic drugs(herbal or chemical drugs) over the previous 24 hours; lack of sedative drugs or other therapeutic measures (such as the use of vegetable oils, regular exercise) to reduce anxiety before six weeks; Desire for pregnancy.
Exclusion criteria: Not to have tendency to continue participating in the study; Crises and stressful events during the study; Lack of regular use of aromatherapy; Other signs like diarrhea that show nausea and vomiting are pathological; Each disease which makes or increases nausea and vomiting; Use drugs during study; Allergy during aromatherapy.

Age

From **15 years** old to **34 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Ethical commitment of Tehran University of Medical Sciences

Street address

Sixth floor, Central office, Ghods St, Keshavarz Blvd

City

Tehran

Postal code

Approval date

2014-02-17, 1392/11/28

Ethics committee reference number

2478/130/92/ص

Health conditions studied

1

Description of health condition studied

Nausea and vomiting of pregnancy

ICD-10 code

Z34.9

ICD-10 code description

Supervision of normal pregnancy, unspecified

2

Description of health condition studied

Anxiety in Pregnancy

ICD-10 code

F40, F41,

ICD-10 code description

Neurotic, stress-related and somatoform disorders

Primary outcomes

1

Description

vomiting distress

Timepoint

every 24 hours

Method of measurement

Rhodes index

2

Description

anxiety

Timepoint

before intervention and one week after the intervention
(End of intervention)

Method of measurement

Spielberg State Anxiety Inventory questionnaire.

3

Description

duration of nausea

Timepoint

every 24 hours

Method of measurement

Rhodes index

4

Description

frequency of nausea

Timepoint

every 24 hours

Method of measurement

5**Description**

distress from retching

Timepoint

every 24 hours

Method of measurement

Rhodes index

6**Description**

frequency of retching

Timepoint

every 24 hours

Method of measurement

Rhodes index

7**Description**

amount of vomiting

Timepoint

every 24 hours

Method of measurement

Rhodes index

8**Description**

distress of nausea

Timepoint

every 24 hours

Method of measurement

Rhodes index

9**Description**

frequency of vomiting

Timepoint

every 24 hours

Method of measurement

Rhodes index

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: Participants will be dropped Lavender oil (made by Barij Company) on a piece of cotton pad and will attach to their dress collar within 20 cm distance from nose and they will breathe normally for 20 minutes. This process continues 2 times a day for 1week.

Category**2****Description**

intervention group 2: Participants will be dropped Mint oil (made by Barij Company) on a piece of cotton pad and will attach to their dress collar within 20 cm distance from nose and they will breathe normally for 20 minutes. This process continues 2 times a day for 1week

Category

Treatment - Drugs

3**Description**

control group(placebo): Participants will be dropped Sesame oil (made by Barij Company) on a piece of cotton pad and will attach to their dress collar within 20 cm distance from nose and they will breathe normally for 20 minutes. This process continues 2 times a day for 1week.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Baharloo hospital

Full name of responsible person

Maryam keshavarz

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Behdari St, Rah Ahan Sq

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

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr Fotoohi Akbar

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Sixth floor, Central office, Ghods St, Keshavarz Blvd, Tehran

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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

Vice chancellor for research, Tehran 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

Tehran University of Medical Science

Full name of responsible person

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Position

MA

Other areas of specialty/work

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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