Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 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. Alsoby 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

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Maryam Keshavarz
Name of organization / entity
Iran University of Medical Sciences
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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; Alergy 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 somutoform disorders

Primary outcomes

1

Description
vomiting distress

Timepoint
every 24 hours

Method of measurement
Rhodez 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

Rhodes index

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
Treatment - Drugs

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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Tehran
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

Azam Amzajerdi

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