

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Determination the effect of inhaled peppermint aroma on the severity of nausea and vomiting of pregnancy in women

Protocol summary

Summary

This study is a randomized single-blind controlled clinical trial that aimed to determine the effects of inhaling peppermint aroma on the severity of nausea and vomiting of pregnancy that will include 56 pregnant women (28 patients in the intervention group and 28 patients in the control group) with following criteria : Age 18 to 35 years, Iranian and has the ability to read and write, basic level of nausea and vomiting according to (PUQE) questionnaire before intervention in range mild to moderate (points 12-3), 6 to 20 weeks of gestational age, non-smoker and non-alcoholic, lack of sensitivity to herbal medicines according to her manifest. Pregnant women in the event of severe nausea and vomiting of pregnancy, allergic to peppermint oil and signs of threatened abortion will be excluded. In both groups, inhaling aromatherapy will be done over a period of four days. Women in intervention group at the time of nausea will pour 5 drops of Peppermint essential oil on a cotton ball and put it 0.5 centimeter below their nose then will inhale three deep breaths through the nose. Aromatherapy in the control group will perform similarly with sweet almond oil. Finally, to determine the severity of nausea and vomiting, pregnant women will fill out PUQE questionnaire at the end of each day and will deliver them to the researcher after the end of the intervention period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412043860N9**

Registration date: **2014-12-31, 1393/10/10**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-12-31, 1393/10/10

Registrant information

Name

Gity Ozgoli

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2512

Email address

gozgoli@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Nursing and Midwifery college of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination the effect of inhaled peppermint aroma on the severity of nausea and vomiting of pregnancy in women

Public title

Effect of peppermint aroma on the severity of nausea and vomiting of pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 18-35 years, Iranian and has the ability to read and write, Basic severity of nausea and vomiting according to (PUQE) questionnaire before intervention in range mild to moderate (score 3-12), 6 to 20 weeks of gestational age (based on the first day of the last menstrual period or first trimester sonography), Having at least one sonography to determine the number and health of the fetus, Wanted pregnancy, The lack of sense of smell problems, A normal single pregnancy in every respect and without a history of obstetric complications during pregnancy (no symptoms of threatened abortion, lack of molar pregnancy), Healthy pregnant women without a history of known diseases according to the information in the maternal health file, Non-smoker and non-alcoholic, Lack of sensitivity to herbal medicines according to her, Avoiding the use of any chemical or herbal antiemetics during the 24 hours before the start of study, Lack of mental health problems and disaster during the six months before the start of study according to her. Exclusion criteria: Severe nausea and vomiting of pregnancy (scoring 13 or higher according to PUQE questionnaire) during the study period, Allergic to peppermint essential oil or peppermint fragrance intolerance, Use any chemical or herbal antiemetics, Aromatherapy less than three times during the day, Signs and symptoms of threatened abortion during the study period, Unwillingness to continue to participate in the study. Exclusion criteria: severe nausea and vomiting of pregnancy (scoring 13 or higher according to PUQE questionnaire), allergic to peppermint oil or peppermint fragrance intolerance, use any chemical or herbal anti-nausea medication, signs and symptoms of threatened abortion during the study period, unwillingness to continue to participate in the study.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, next to Talqany hospital, Yaman street, Shahid Chamran highway, Tehran

City

Tehran

Postal code

1985717443

Approval date

2014-11-23, 1393/09/02

Ethics committee reference number

161

Health conditions studied

1

Description of health condition studied

Nausea and vomiting of pregnancy

ICD-10 code

O21.0

ICD-10 code description

Mild hyperemesis gravidarum

Primary outcomes

1

Description

severity of nausea and vomiting of pregnancy

Timepoint

Before the intervention, after the intervention at the end of each day for 4 days.

Method of measurement

The Pregnancy Unique Quantification of Emesis/Nausea questionnaire

Secondary outcomes

1

Description

Satisfaction of the treatment course

Timepoint

At the end of intervention period (after 4 days)

Method of measurement

Researcher made questionnaire at the end of intervention

2

Description

Possible side effects of intervention

Timepoint

At the end of intervention period (after 4 days)

Method of measurement

Researcher made questionnaire at the end of intervention

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

Intervention group: In this group, Aromatherapy with Peppermint essential oil will be done for 4 days. Pregnant women will inhale 1 milliliter of bottle content (containing 2 drops of peppermint essential oil) daily in 4 times and each time 5 drops.

Category

Treatment - Drugs

2**Description**

Control group: The method of aromatherapy in the control group will be the same as intervention group with the difference that in this group sweet almond oil will be used alone.

Category

Placebo

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

Health centers of Shahid Beheshti University of Medical Sciences

Full name of responsible person**Street address****City**

Tehran

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Research Deputy of Nursing and Midwifery College, dr Simbar M

Street address

Vice Chancellor for research of Nursing and Midwifery college of Shahid Beheshti University of Medical Sciences, in front of Shahid Rajaei Heart Hospital, Niayesh intersection, Valiasr Avenue, Tehran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor****organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Nursing and Midwifery college of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Narges Joulaee rad

Position

Graduate student of midwifery

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Nursing and Midwifery college of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Gity Ozgoli

Position

Assistant Professor of Reproductive health

Other areas of specialty/work**Street address**

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Person responsible for updating data

Contact

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