

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of combined inhaler aromatherapy on nausea and vomiting of pregnancy: A randomised controlled trial

Protocol summary

Summary

Objective: determine the effect of combined inhaler aromatherapy (lemon and peppermint) on nausea and vomiting of pregnancy. Design: this study is a randomized controlled trial. Setting and conduct: this study is carried out on pregnant women from the public health centers in Birjand, Iran. Eligible patients who tended to participate are asked to answer the PUQE-24 questionnaire, related to the assessment of NVP in past 24 hours, and if their scores be mild to moderate, after taking written informed consent, will be asked to fill out questionnaire about their demographic and FSS questionnaire. Allocating the participants in the two groups will be done in the random allocation method using computerized random number table and the four and six blocking method with allocation ratio of 1:1. For allocation concealment, dark and similar packaged containers sequentially numbered from one will be used. It will be executed by a person uninvolved in the study. The researcher and participants will be unaware of the content of the containers. The participant will complete PUQE-24 questionnaire daily during 4 days of intervention and at the end of intervention, FSS and final questionnaire will be completed. Participants: 90 Pregnant women with Singleton and normal pregnancy with 6 to 16 weeks gestation; With mild to moderate nausea with or without vomiting (based on 3-12 PUQE-24 scores); Without any antiemetic or emetic drug use in the past 24 hours; Without tobacco use; Without psychological problems and unpleasant event during last 6 months; pregnancy without signs of molar pregnancy and threatened abortion and any other disease with nausea and vomiting as a symptom. Interventions: the participants in both groups when feel nausea, place 3 drops of solution on the cotton, and keep it in distance of 3cm of their nose, and then breathe three times deeply through the nose and if necessary repeat it five minutes later. Main outcome measures variables: Severity of nausea and vomiting of pregnancy and fatigue.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014062914324N2**

Registration date: **2014-09-03, 1393/06/12**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-09-03, 1393/06/12

Registrant information

Name

Farzaneh Safajou

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 1442 2113

Email address

fsafajo@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Birjand University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of combined inhaler aromatherapy on nausea and vomiting of pregnancy: A randomised controlled trial

Public title

The effect of combined inhaler aromatherapy on nausea and vomiting of pregnancy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women who are 16 to 40 years old, with 6 to 16 weeks gestation; With literacy; With Singleton pregnancy; With mild to moderate nausea with or without vomiting (based on 3-12 PUQE-24 scores); Without any antiemetic or emetic drug use in the past 24 hours; Without tobacco use; Without psychological problems and unpleasant event during last 6 months; Pregnancy without signs of molar pregnancy and threatened abortion and pyelonephritis, thyroid dysfunction and digestive diseases and any other disease with nausea and vomiting as a symptom (vomiting according to pregnant women and physician examination); With phone number; Without olfactory disorder (according to patient). Exclusion criteria: Allergy or drug intolerance during intervention; Unwillingness to continue the study; using other drugs during the study.

Age

From **16 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double 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 Birjand University of Medical Sciences

Street address

Ghafari street, Birjand University of Medical Sciences

City

Birjand

Postal code**Approval date**

2014-07-05, 1393/04/14

Ethics committee reference number

1393-04-02

Health conditions studied**1****Description of health condition studied**

Nausea and vomiting of pregnancy

ICD-10 code

O21.0

ICD-10 code description

Hyperemesis gravidarum, mild or unspecified, starting before the end of the 22nd week of gestation

Primary outcomes**1****Description**

Severity of fatigue

Timepoint

Before and after intervention

Method of measurement

FSS questionnaire

2**Description**

Severity of nausea and vomiting of pregnancy

Timepoint

Before and during intervention

Method of measurement

PUQE-24 questionnaire

Secondary outcomes**1****Description**

Side effects

Timepoint

After intervention

Method of measurement

Final questionnaire

2**Description**

Satisfaction

Timepoint

After intervention

Method of measurement

Final questionnaire

Intervention groups

1

Description

Intervention group: Aromatherapy with combined lemon and peppermint essential oil, participants when feel nausea, place 3 drops of solution on the cotton, and keep it in distance of 3cm of their nose, and then breathe three times deeply through the nose

Category

Treatment - Drugs

2

Description

Control group: Aromatherapy with placebo, participants when feel nausea, place 3 drops of solution on the cotton, and keep it in distance of 3cm of their nose, and then breathe three times deeply through the nose

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Health care center number 3

Full name of responsible person

Farzaneh Safajou

Street address

21 Kargaran street, Kargaran street

City

Birjand

2

Recruitment center

Name of recruitment center

Health care center number 4

Full name of responsible person

Farzaneh Safajou

Street address

Sajad Shahr, Ghadir Blvd

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Birjand University of Medical Sciences

Full name of responsible person

Dr Asghar Zarban

Street address

Gafari street, Birjand University of Medical Sciences, Vice chancellor for research

City

Birjand

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, Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Farzaneh Safajou

Position

Master of Sciences in midwifery

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