

# 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 to16 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 dis-ease 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

##### Street address

Ghafari street, Birjand University of Medical Sciences, Faculty of Nursing and Midwifery

##### City

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+98 56 1882 5000

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##### Web page address

## Person responsible for scientific inquiries

#### Contact

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Master of Sciences in midwifery

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## Person responsible for updating data

### Contact

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Birjand University of Medical Sciences  
**Full name of responsible person**  
Farzaneh Safajou  
**Position**  
Master of Sciences in midwifery  
**Other areas of specialty/work**  
**Street address**  
Ghafari street, Birjand University of Medical Sciences,  
Faculty of Nursing and Midwifery  
**City**  
Birjand  
**Postal code**

## 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*