Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Siences
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Iran (Islamic Republic of)
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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 to16 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 dis¬ease 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 Siences

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
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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 Siences, 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 Siences
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Person responsible for scientific inquiries

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Person responsible for updating data

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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