Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Summary

The aim of this study is to determine the effect of lemon inhaler aromatherapy on nausea and vomiting of pregnancy. We will recruit pregnant woman from the public health centers in Birjand, Iran. Pregnant woman that have eligible criteria will compelet PUQE-24 questionnaire which assess the severity of nausea and vomiting over the previous 24 hour. After getting written informed consent, we will randomly allocate them into intervention and control groups with assignment ratio of 1:1 using permuted block randomization with block sizes of four and six. For allocation of concealment we will use in sequentially numbered identical containers that are administered serially to participants. In this study we keep blinding for participants and researcher. in two group Once the feeling of nausea 2 drop of solution are placed on the cotton and held 3 cm under nose. Participant were instructed to take three slow, deep breaths and if necessary, repeat it after 5 minute. The participant will compelet PUQE-24 questionnaire daily during 4 days of intervation and at the end of intervention, researcher will complete the final questionnaire and the difference of mean in severity of nausea and vomiting are compared before and after of intervention and among two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202297418N2**
Registration date: **2012-05-10, 1391/02/21**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-05-10, 1391/02/21

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Nursing and Midwifery Faculty of Tabriz University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2012-10-22, 1391/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

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

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 16 to 40 years old; Singleton and normal pregnancy with 6 to16 weeks based on LMP and ultrasound; Being able to compelet questionnaire;

Having mild to moderate nausea and vomiting without hyperemesis gravidarum symptoms (based on 3-12 PUQE-24 scores); Not using anti emetic or emetic drugs(herbal or chemical drugs) over the previous 24 hour; Not having psychological problems and unpleasant event over 6 months ago according to pregnant women reporting; Not using tobacco; Not having molar pregnancy; Not having symptoms of Threatened abortion; Not having acute Pyelonephritis; Not having thyroid dysfunction; Not having identified digestive diseases which may cause nausea and vomiting; Having phone; No olfactory disorder. Exclusion criteria: Alergy during aromatherapy; use anti emetic herbal or chemical drugs during study

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **25**

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
Research Deputy of Tabriz University of Medical Sciences

Street address
Tabriz- Golgasht st-Tabriz University Of Medical Sciences-No 2 Building -3 floor -Deputy Of Research

City
Tabriz

Postal code
51665118

Approval date
2012-03-12, 1390/12/22

Ethics committee reference number
916

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 nausea and vomiting of pregnancy

Timepoint
Before and during intervention

Method of measurement
24-hour Pregnancy Unique Quantification of Emesis

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 essential oil, Once the feeling of nausea 2 drop of solution are placed on the cotton and held 3 cm under nose. Participant were instructed to take three slow, deep breaths and if necessary, repeat it after 5 minute.

Category
Other

2

Description
Control group:The use of placebo(normal salin): Once the feeling of nausea 2 drop of solution are placed on the cotton and held 3 cm under nose. Patients were

instructed to take three slow, deep breaths and if necessary, repeat it after 5 minute.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Zahra health care center

Full name of responsible person

Farzaneh Safajou

Street address

21 Kargar street

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

Golgashat Street, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Deputy of Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

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Position

Master of sciences student in midwifery

Other areas of specialty/work

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Web page address

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