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 complete 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 complete PUQE-24 questionnaire daily during 4 days of intervention 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: 0
Registration date 2012-05-10, 1391/02/21

Registrant information
Name
Parisa Yavarikia
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1479 6770
Email address
yavarikiap@tbzmed.ac.ir

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 complete 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: Allergy 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
empty
Type of organization providing the funding
empty

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University Of Medical Sciences
Full name of responsible person
Parisa Yavarikia
Position
Master of Sciences in midwifery
Other areas of specialty/work
Street address
Faculty of Nursing and Midwifery, South Shariati street
City
Tabriz
Postal code
Phone
+98 41 1479 6770
Fax
Email
yavarikiap@tbzmed.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University Of Medical Sciences
Full name of responsible person
Farzaneh Safajou
Position
Master of sciences student in midwifery

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