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

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

**Health conditions studied**

1. **Description of health condition studied**
   - Nausea and vomiting of pregnancy

2. **ICD-10 code**
   - O21.0

3. **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

2. **Timepoint**
   - Before and during intervention

3. **Method of measurement**
   - 24-hour Pregnancy Unique Quantification of Emesis

**Secondary outcomes**

1. **Description**
   - Side effects

2. **Timepoint**
   - After intervention

3. **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.

2. **Category**
   - Other

3. **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**  
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**  
Faculty of Nursing and Midwifery, South Shariati street  
**City**  
Tabriz  
**Postal code**  
+98 41 1479 6770  
**Phone**  
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