Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of inhaled aromatherapy with rose and metoclopramide on nausea and vomiting in pregnancy in Pregnant women

Protocol summary

Study aim

A Comparative Study of the Effects of Rose and Metoclopramide on Nausea and Vomiting due to Pregnancy

Design

In this assessment, 40 pregnant women with inclusion criteria were included in the study. Participants are randomly coded and classified. Based on this, patients are divided into two treatment groups.

Settings and conduct

In this assessment, in one group, in the Pilot form during nausea and vomiting attacks, place two drops of Rose Essence on the napkin and place it near to the nose within three centimeters interval and ask the patient to breath 3 seconds through the nose and take 15 drops of placebo in three time, and in the other group we used of 15 drops of metoclopramide drop by three times (6 am, 1 pm and 9 o'clock) with placebo, as an inhaled nasal spray. Then patients are evaluated after 5 days of treatment. Then, the data from treatment in both groups. This is a double-blind study, Therefore, patient and researcher do not know dividing approach and treatment groups and their classification is based on coding.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Women with first and second pregnancies who have mild to moderate Longing, between 7 and 14 weeks of gestation. Exclusion Criteria: Systemic disease and complications of pregnancy.

Intervention groups

In one group we have use of herbal remedies, and in the other group, metoclopramide has used as an interventional medicine.

Main outcome variables

nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170628034792N4**
Registration date: **2018-02-23, 1396/12/04**
Registration timing: **retrospective**

Last update: **2018-02-23, 1396/12/04**
Update count: **0**

Registration date

2018-02-23, 1396/12/04

Registrant information

Name

bahare mohammadipour yazdi

Name of organization / entity

mashhad university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 913 633 0656

Email address

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Recruitment status

Recruitment complete

Funding source

mashhad university of medical science

Expected recruitment start date

2017-07-16, 1396/04/25

Expected recruitment end date

2017-09-16, 1396/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of inhaled aromatherapy with rose and metoclopramide on nausea and vomiting in pregnancy in Pregnant women

Public title
Comparison of the effect of rose and metoclopramide on nausea and vomiting in pregnancy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
women with first and second intentionally pregnancy between 7 to 14 weeks of gestation mild to moderate nausea and vomiting nausea and vomiting have not improved with diet and usual dietary regimens not having other systemic diseases and multiple pregnancies mild to moderate Longing

Exclusion criteria:
Hepatitis, gastritis, increased intracranial pressure and pancreatitis complications of pregnancy including threatened abortion bleeding pyelonephritis. requirement the person to take medication

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Randomized block randomized allocation method has been used. Accordingly, patients are divided into two groups. Randomization Units: The randomization unit of the patients was as groups and patients are separated based on this. Randomization tools: for separation of patients we have used the relevant tables.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to blind the study, patients in each group of other therapeutic groups had no information. The choice of patients was based on the numbering of the checklist, and the researcher did not know the type of treatment performed in patients. Accordingly, this study was double blinded.

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic's committee of Mashhad University of Medical Science

Street address
9177948564, Mellat Park, Vakilabad Boulevard, Mashhad

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Province
Razavi Khorasan

Postal code
9177948564

Approval date
2016-06-22, 1395/04/02

Ethics committee reference number
ir.mums.fm.rec.1395.88

Health conditions studied

1

Description of health condition studied
nausea and vomiting during pregnancy

ICD-10 code
021.0

ICD-10 code description
nausea and vomiting of pregnancy

Primary outcomes

1

Description
nausea and vomiting

Timepoint
In 5 days after treatment and three times per day

Method of measurement
visual scale and Rhodes Index 1 to 10

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group was 20 cases, in which the Rose Essence was piloted by the patient during nausea and vomiting attacks. Two drops of Rose Essence are placed on the napkin and three centimeters away from the nose and the patient is asked to breathe for

three seconds, in addition they are asked to take 15 drops of the placebo three times.

Category

Treatment - Drugs

2

Description

Control group: The other group was 20, in which 15 ml of drop of metoclopramide droppings were used for three times (6 am, 1 pm and 9 am) with placebo essential oil inhalation at nausea time.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza and Omol Banin hospitals

Full name of responsible person

Malihe Safi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

mashhad university of medical science department of gynecology

Full name of responsible person

Dr.Malihe Afiat

Position

Assistant Professor of Obstetrics and Gynecology

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Full name of responsible person

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Latest degree

Specialist

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Full name of responsible person
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Assistant Professor of Obstetrics and Gynecology

Latest degree
Specialist

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available