

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 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

mohammadipourb881@mums.ac.ir

##### 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

**City**

mashhad

**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

**Street address**

9177948564, Mellat Park, Vakilabad Boulevard, Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Phone**

+98 51 3882 8888

**Fax**

**Email**

afiatm@mums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

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

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Phone**

+98 51 1801 2851

**Email**

layeghpo@mums.ac.ir

**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

**Street address**

9177948564, Ibn Sina St, The margin of Imam Reza Square (AS), Mashhad,

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Phone**

+98 51 3802 2000

**Fax**

**Email**

afiatm@mums.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Department of Obstetrics and Gynecology, Mashhad University of Medical Sciences

**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

**Street address**

Imam Reza hospital

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Phone**

+98 51 3802 2000

**Fax**

**Email**

afiatm@mums.ac.ir

**Web page address**

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Phone**

+98 51 3882 8888

**Email**

afiatm@mums.ac.ir

## 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

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Department of Obstetrics and Gynecology, Mashhad  
University of Medical Sciences

**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

**Street address**

9177948564, Ibn Sina Avenue, on the edge of Imam  
Reza Square (AS), Mashhad