

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The comparison of the effect of bitter orange and ondansetron on treatment of nausea and vomiting in pregnant women between weeks 6 till 20 of pregnancy

Protocol summary

Study aim

The comparison of the effect of bitter orange peel and ondansetron on treatment of nausea and vomiting in pregnant women between weeks 6th and 20th of pregnancy

Design

Clinical trial with control group; with parallel groups; double blinded; randomized; design of 80 patients

Settings and conduct

Patient will be assigned into 2 groups with block randomization method, 40 patients will be treated by ondansetron and 40 patients will be received bitter orange peel. Both groups will also request to fill in a questionnaire before start and after two weeks of treatment. Drugs are named to A and B and have been administered in the similar bottle. The participants complete the questionnaire based on their responses to questions about general changes in nausea and vomiting, method of drugs were taken and complete SF-36 questionnaire after treatment too.

Participants/Inclusion and exclusion criteria

Inclusion criteria include gestational age between 6-20 weeks of pregnancy, having mild to moderate nausea and vomiting without a need of hospitalization, singleton pregnancy with a live normal fetus, not having any known gastrointestinal disorder, without a history of smoking or drug use, lack of a known mental illness such as severe anxiety and depression, and not having any known allergy or hypersensitivity to herbal medications. Exclusion criteria are having any other symptoms showing pathologic problems, having any known gastrointestinal or any other systemic disorder or any drug use except common supplementation

Intervention groups

80 subjects with nausea and vomiting of pregnancy disorder will be assigned into 2 groups with block randomization method, 40 patients will be treated by

ondansetron and 40 patients will be received bitter orange peel.

Main outcome variables

Intensity of nausea and vomiting, Quality of life score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140525017827N11**

Registration date: **2021-08-14, 1400/05/23**

Registration timing: **prospective**

Last update: **2021-08-14, 1400/05/23**

Update count: **0**

Registration date

2021-08-14, 1400/05/23

Registrant information

Name

Nasrin Asadi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1233 2365

Email address

asadin@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of bitter orange and ondansetron on treatment of nausea and vomiting in pregnant women between weeks 6 till 20 of pregnancy

Public title

The comparison of the effect of bitter orange and ondansetron on treatment of nausea and vomiting of pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

gestational age between 6-20 weeks of pregnancy (according to a reliable LMP and ultrasound confirmation of the first trimester) Having mild to moderate nausea and vomiting without a need of hospitalization Singleton pregnancy with a live normal fetus Not having any known gastrointestinal disorder Without a history of smoking or drug use Lack of a known mental illness such as severe anxiety and depression Not having any known allergy or hypersensitivity to herbal medications

Exclusion criteria:

Severe nausea and vomiting needing hospitalization No acceptance for herbal medicine Having any other symptoms showing pathologic problems such as diarrhea Having any known gastrointestinal or any other systemic disorder or any drug use except common supplementation (folic acid)

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

The treatment allocation list is already designed on Block Balanced Randomization Method by software (<https://mahmoodsaghaei.tripod.com/Softwares/ranalloc.html>) (A), 2 (B), 3 (B), 4 (B), 5 (A),..... Any eligible patient will be given a 1 to 80 code after obtaining informed consent in order to visit the clinic and based on above block, they receive A or B drug.

Blinding (investigator's opinion)

Double blinded

Blinding description

Ondansetron and bitter orange peel have been administered in the similar bottles, so patients and researchers were unable to detect which one was Ondansetron or bitter orange peel. Our nurse colleague in this study in hospital delivered formulations to the participants of the study according to Block Balanced Randomization Method by software. She was unaware of the content of the bottles. The researcher had no information about formulation used by each patient while visiting them. At the end of the study, the formulations were decoded and the patients assigned to each group were identified.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Committee of Shiraz University of Medical Sciences

Street address

Headquarters Of Shiraz University of Medical Sciences
- Zand St - Shiraz

City

Shiraz

Province

Fars

Postal code

34786-71946

Approval date

2021-06-27, 1400/04/06

Ethics committee reference number

IR.SUMS.MED.REC.1400.185

Health conditions studied**1****Description of health condition studied**

Nausea & vomiting in pregnancy

ICD-10 code

O21.9

ICD-10 code description

Vomiting of pregnancy, unspecified

Primary outcomes**1****Description**

Intensity of nausea and vomiting
Timepoint
Before start and two weeks later of treatment
Method of measurement
Visual analog scale

Secondary outcomes

1

Description
Quality of life score
Timepoint
Before start and two weeks later of treatment
Method of measurement
Short Form 36 Health Survey (SF-36)

Intervention groups

1

Description
Intervention group: Treatment of one group with bitter orange
Category
Treatment - Drugs

2

Description
Intervention group: The other group with ondansetron
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat zeynab Clinic of Shiraz University of Medical Sciences
Full name of responsible person
Farrokh khani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shiraz 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
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Full name of responsible person
Farrokh khani
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Resident of obstetrics and gynecology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Statistical Results

When the data will become available and for how long

6 month after the project completion

To whom data/document is available

By obtaining a license from the ethics committee and for scientific and research use in coordination with the main researchers

Under which criteria data/document could be used

The data is for use in this design only. If necessary, after obtaining the necessary permits from the ethics committee

From where data/document is obtainable

To researchers responsible for responding to this plan

What processes are involved for a request to access data/document

Written request Coordinated by the ethics committee 2 months

Comments