Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 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/randalloc.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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Square defae moghaddas

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7153813311

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Reazaeian Zade

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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

Shiraz University of Medical Sciences

Full name of responsible person

Farrokh khani

Position

Resident of obstetrics and gynecology

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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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