Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Comparing Ondansetron and Ginger for the treatment of nausea and vomiting in pregnancy on pregnant women attending prenatal clinic

Protocol summary

Study aim
The aim of this study was to compare the effect of ondansetron and ginger for nausea and vomiting of pregnancy.

Design
Clinical trial without control group, with parallel groups, three-way blind, simple randomized, phase 3 on 150 patients

Settings and conduct
The statistical population in this study is all pregnant women referred to the prenatal clinic of Booali Hospital in Tehran who have mild to moderate nausea and vomiting according to the questionnaire.The study of the sampling method is first done in an improbably easy method and among the available samples with inclusion criteria, then the units are randomly divided into two comparative groups of ginger, ondansetron and consumption.

Participants/Inclusion and exclusion criteria
Gestational age 6-16 weeks, With mild to moderate nausea and vomiting Single pregnancy, No Known insensitivity to ginger and ondansetron, No known underlying disease, No risk of pregnancy, Do not take anticoagulants

Intervention groups
Solid capsules will be filled and encoded by ondansetron powder, ginger. Ginger capsules contain 500 mg of ginger root powder and ondansetron capsules contain 8 mg of this drug powder. Each sample will be given an envelope with a specific code and in the same package, each of which contains 12 capsules. The method of taking the drug is one capsule every 12 hours for up to 4 days. People will record the severity of their nausea and vomiting every day based on the questionnaire.

Main outcome variables
Dependent variables: Severity of nausea, Severity of vomiting, Complications

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210303050564N1**
Registration date: **2021-04-14, 1400/01/25**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-14, 1400/01/25**
Update count: **0**

Registration date
2021-04-14, 1400/01/25

Registrant information

Name
Marjan Akhavan Amjadi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 2270 0769

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marjan_akhavan2003@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-09, 1400/01/20

Expected recruitment end date
2021-08-11, 1400/05/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing Ondansetron and Ginger for the treatment of nausea and vomiting in pregnancy on pregnant women attending prenatal clinic

Public title
Comparing Ondansetron and Ginger for the treatment of nausea and vomiting in pregnancy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Gestational age 6-16 weeks Mild to moderate nausea and vomiting Single pregnancy
Exclusion criteria:
Known underlying disease Risk of pregnancy Take anticoagulants Known insensitivity to ginger and ondansetron
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple random
Blinding (investigator's opinion)
Triple blinded
Blinding description
Each sample will be given an envelope with a specific code and in the same package, each of which contains 12 capsules. It should be noted that based on the three-sided blindness of the research, the researcher, research units and statisticians will not know any of the drugs used.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences, Tehran
Street address
Nyaiesh, Hashemi Rafsanjani Bulvar, Valiasr Ave
City
Tehran
Province
Tehran
Postal code
3817-14155
Approval date
2021-01-29, 1399/11/10
Ethics committee reference number
IR.SBMU.RETECH.REC.1399.1009

Health conditions studied

1

Description of health condition studied
Nausea and vomiting in pregnancy
ICD-10 code
O21.0
ICD-10 code description
O21.0 Mild hyperemesis gravidarum

Primary outcomes

1

Description
The severity of nausea and vomiting
Timepoint
Measure the severity of nausea and vomiting at the beginning of the study and daily during treatment
Method of measurement
Rhodes Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: ondansetron Ondansetron powder is prepared from a pharmaceutical company. Then, in Tehran Shahid Beheshti School of Pharmacy, monochromatic capsules will be filled and coded with 8 mg of ondansetron powder. Each sample will be given an envelope with a specific code and in the same package, each of which contains 12 capsules. They will not know the type of medicine used. The method of taking the drug is one capsule every 12 hours for up to 4 days. People will record the severity of their nausea and vomiting every day based on the questionnaire.
Category
Treatment - Drugs

2

Description

Intervention group: ginger Ginger root powder is prepared from a reputable center. Then, in Tehran Shahid Beheshti School of Pharmacy, monochromatic capsules will be filled and coded with 500 mg of ginger root powder. Each sample will be given an envelope with a specific code and in the same package, each of which contains 12 capsules. They will not know the type of medicine used. The method of taking the drug is one capsule every 12 hours for up to 4 days. People will record the severity of their nausea and vomiting every day based on the questionnaire.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Prenatal Clinic of Bu Ali Hospital
Full name of responsible person
Faraz Mojab
Street address
The Beginning of Damavand Street, Imam Hossein Square
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Maria Tavakoli Ardakani
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Vali Asr St. Niayesh Cross Section
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Faraz Mojab
Position
professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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Position
Assistant Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Total data

When the data will become available and for how long
6 months after printing the results

To whom data/document is available
For academics

Under which criteria data/document could be used
Academic use

From where data/document is obtainable
marjan_akhavan2003@yahoo.com

What processes are involved for a request to access data/document
Up to one month after making the call

Comments