Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Comparison The effect of Ondansetron versus Ginger on Nausea and Vomiting in pregnancy

Protocol summary

Study aim
The aim of this study is to Compare the effect of Ginger with Ondanstron on Nausea and Vomiting in pregnancy.

Design
This study is a randomized double-blind clinical trial with two intervention and control groups (with parallel design)

Settings and conduct
This is a double-blind clinical trial conducted on 116 pregnant women referred to Mahshahr health centers who suffer from moderate and severe gestational nausea and vomiting.Drugs are sealed to the required number for each group inside numbered brown bag, which matches to the number of patients. A special code is assigned to each bag and drug package. Putting pills into the brown bag and numbering them is done by someone outside of the research team. In this research, the patient, the researcher, and the providers of medical services are blinded to the pharmaceutical diet.

Participants/Inclusion and exclusion criteria
The inclusion criteria include: Age between 18-35 years; Gestational age of 10-15 weeks; Single pregnancy ; LMP or ultrasound precision; Ability to read and write. The exclusion criteria include: The presence of diseases such as kidney, high blood pressure, epilepsy, diabetes and hepatitis, digestive diseases;Unwanted pregnancy; Malignant vomiting of pregnancy; Smoking; Symptoms of abortion; Infertility; Undesirable events in the past; Taking iron pills over the past week; The patient has used anti-nausea and vomiting drugs for at least 3 days; Sensitivity to ginger.

Intervention groups
Control group: administration of Ginger tablet, 500 mg, every 8 hours for three days Intervention group: administration of Ondanstron tablet, 4 mg, every 8 hours for three days

Main outcome variables
Nausea; Vomiting

General information

Reason for update

Acronym
NVP

IRCT registration information
IRCT registration number: **IRCT20171007036600N1**
Registration date: **2018-02-18, 1396/11/29**
Registration timing: **prospective**

Last update: **2018-02-18, 1396/11/29**
Update count: **0**

Registration date
2018-02-18, 1396/11/29

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 61 5235 8388
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khalilimoghadam.z@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-20, 1396/12/01

Expected recruitment end date
2018-06-21, 1397/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison The effect of Ondansetron versus Ginger on Nausea and Vomiting in pregnancy

Public title
Ginger and Ondansetron tablets on Nausea and Vomiting in pregnancy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18-35 years Gestational age 10-15 weeks Single pregnancy knowing the exact time of last menstrual period (LMP) or having a precised sonographic result Ability to read and write

Exclusion criteria:
The presence of diseases such as kidney disease, high blood pressure, epilepsy, diabetes and hepatitis, digestive diseases that may lead to nausea and vomiting Unwanted pregnancy Severe vomiting in pregnancy Smoking Symptoms of abortion; miscarriage or molar pregnancy Pregnancy following infertility Undesirable events in the past, such as severe disagreement with a partner, death of spouse or first degree relatives Consuming agents such as iron that exacerbate nausea and vomiting during the last week Consuming anti-inflammatory drugs for at least 3 days Sensitivity to ginger

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **116**

Randomization (investigator's opinion)
Randomized

Randomization description
Table of random numbers using the computer - on an individual basis

Blinding (investigator's opinion)
Double blinded

Blinding description
Drugs are sealed to the required number for each group inside numbered brown bag, which matches to the number of patients.A special code is assigned to each bag and drug package. Putting pills into the brown bag and numbering them is done by someone outside of the research team. In this research, the patient, the researcher, and the providers of medical services are blinded to the pharmaceutical diet.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committe of Ahvaz JundiShapur University of Medical Sciences

Street address
اهواز، شهر دانشگاهي ، معاونت توسعه پژوهش و فن آوری دانشگاه علوم پزشكي و خدمات بهداشتی درمانی جندی شاپور اهواز

City
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Province
Khouzestan

Postal code
61357-15794

Approval date
2017-11-21, 1396/08/30

Ethics committee reference number
IR.AJUMS.REC.1396.618

Health conditions studied

1

Description of health condition studied
Nausea and Vomiting in pregnancy

ICD-10 code
O21.9

ICD-10 code description
Vomiting of pregnancy, unspecified

Primary outcomes

1

Description
severity of Nausea

Timepoint
Before intervention and three days after that

Method of measurement
Rodes standard questionnaire

2

Description
Rate of Nausea

Timepoint
Before intervention and three days after that

Method of measurement
Rodes standard questionnaire

3

Description
Duration of Nausea

Timepoint
Before intervention and three days after that
Method of measurement
Rodes standard questionnaire

4

Description
Severe Vomiting
Timepoint
Before intervention and three days after that
Method of measurement
Rodes standard questionnaire

5

Description
Rate of Vomiting
Timepoint
Before intervention and three days after that
Method of measurement
Rodes standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control group: administration of Ginger tablet, 500 mg, every 8 hours for three days
Category
Treatment - Drugs

2

Description
Intervention group: administration of Ondanstron tablet, 4 mg, every 8 hours for three days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Health center of Mahshahr city
Full name of responsible person
Zahra khalili Moghadam
Street address
Mahshahr Imam Musa Kazem Hospital, In front of overpass, After the bus terminal
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Badavi
Street address
Ground floor, vice chancellor for research, Ahvaz Junishapur University of Medical Science and Health Services, Shahre Daneshgahi, Ahvaz
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Mitra Tadayon Najafabady
Position
Master of Science

Latest degree
Master
Other areas of specialty/work
Midwifery
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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