

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

Email address

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 committee of Ahvaz JundiShapur University of Medical Sciences

Street address

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

City

اهواز

Province

Khuzestan

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

City

Mahshahr

Province

Khuzestan

Postal code

6351984406

Phone

+98 61 5232 6051

Fax

+98 61 5235 8388

Email

khalilimoghadam.z@ajums.ac.ir

Web page address**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

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Phone

+98 61 3373 8383

Fax

+98 61 3361 5443

Email

itc@ajums.ac.ir

Web page address**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

Street address

School of Nursing and Midwifery, JundiShapur
University of Medical Sciences, Golestan boulevard,
Ahvaz

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3373 8331

Fax

+98 61 3373 8333

Email

mitratadayon2000@yahoo.com

Web page address**Person responsible for scientific 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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School of Nursing and Midwifery, JundiShapur
University of Medical Sciences, Golestan boulevard,
Ahvaz

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3373 8331

Fax

+98 61 3373 8333

Email

mitratadayon2000@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Zahra khalili Moghadam

Position

Master student in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, JundiShapur
University of Medical Sciences, Golestan boulevard,
Ahvaz

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Phone

+98 61333738331

Fax

+98 61 3373 8333

Email

khalilimoghadam.z@ajums.ac.ir

Web page address**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