

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

A comparison of Ondansetron vs. Metoclopramide for treatment of nausea and vomiting in pregnancy

Protocol summary

Summary

Nausea and vomiting are present in 50-90% of pregnancy. Sever form of the disease with 5% loss of body weight can cause morbidity during pregnancy. This study evaluates Ondansetron and Metoclopramide for treatment of nausea and vomiting in pregnancy. One hundred pregnant women enroll the study according to inclusion and exclusion criteria. Following laboratory tests will be checked for them: TSH, BG & RH, CBC, LFT, FBS, Na-K, BUN, Cr and urine Ketone. They will receive 10mg of Metoclopramide or 2mg of Ondansetron two times a day. The severity of nausea and the number of vomiting episodes will be recorded in the last 24 hours before and during treatment and again after one week of cessation of treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902161760N6**

Registration date: **2010-05-06, 1389/02/16**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2010-05-06, 1389/02/16

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health
Research Center, Babol University of Medical
Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Babol
University of Medical Sciences

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-04-21, 1390/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of Ondansetron vs. Metoclopramide for
treatment of nausea and vomiting in pregnancy

Public title

A comparison of Ondansetron vs. Metoclopramide for
treatment of nausea and vomiting in pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: pregnant women with gestational age less than 16 weeks based on the last menstrual period and ultrasound, with symptoms of vomiting for more than three times a day, or weight loss more than three kilograms or positive urine ketones. Exclusion criteria: presence of internal diseases at the same time, and hydatidiform mole and twin pregnancy.

Age

From **20 years** old to **35 years** old

Gender

Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethics committee of Babol University of Medical sciences

Street address

Babol University of Medical sciences, Gangafoz Avenue

City

Babol

Postal code

4717641367

Approval date

2010-07-03, 1389/04/12

Ethics committee reference number

1017

Health conditions studied

1

Description of health condition studied

Severe nausea and vomiting of pregnancy

ICD-10 code

O21

ICD-10 code description

Excessive vomiting in pregnancy

Primary outcomes

1

Description

Improvement of clinical symptoms

Timepoint

Before and after treatment

Method of measurement

Based on VAS

Secondary outcomes

1

Description

Recurrence rate of nausea and vomiting

Timepoint

One week after discontinuation

Method of measurement

Based on VAS

Intervention groups

1

Description

Metoclopramide (10mg)

Category

Treatment - Drugs

2

Description

Ondansetron (2mg)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yahyanejad Hospital

Full name of responsible person

Marziyeh Zanganeh

Street address

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Full name of responsible person

Ali Bijani

Street address

Gangafoz Avenue

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding sourceVice Chancellor for Research and Technology, Babol
University of Medical Sciences**Proportion provided by this source**

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**Fatemehzahra Fertility & Reproductive Health
Research Center**Full name of responsible person**

Nargess Gholizadeh Pasha

Position

M.A/Responsible of Research Center

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Research Center**Full name of responsible person**

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Position

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty***Person responsible for scientific inquiries****Contact****Name of organization / entity**Fatemehzahra Fertility & Reproductive Health
Research Center**Full name of responsible person**

Dr. Zahra Basirat

Position

Gynecologist

Other areas of specialty/work**Street address**