Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Metoclopromide 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

+98 11 3236 2282

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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, Gangafroz 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
Babol

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
Gangafroz 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 source
Vice 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
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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