

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of Effectiveness of Ondansetron versus Metoclopramide in Hyperemesis Gravidarum

Protocol summary

Study aim

determination of the effect of ondansetron and metoclopramide on nausea and vomiting of pregnancy

Design

double blind randomised clinical trial of 154 patients randomly will be divided into two groups of 77 patients by coin throwing and accidental drug administration to patients by a third party(nurse) that does not directly play a role in conducting the study.Since both drugs are colorless, patients are not aware of the type of injectable drug, and only the nurse is aware of the prescription drug, and the patients are classified into two groups of one and two.

Settings and conduct

All pregnant women who will be admitted with nausea and vomiting of pregnancy in the obstetrics and maternal ward of Mousavi Hospital in Zanjan will be enrolled and randomly divided into two groups: Endonestrone and Metoclopramide.

Participants/Inclusion and exclusion criteria

Inclusion criteria: clinical signs of nausea, vomiting and dehydration, gestational age less than 16 weeks from the first day of the last menstruation, ketonuria, oral intolerance. Exclusion criteria: gastrointestinal disorders justify nausea and vomiting, multiple pregnancy, having certain diseases , such as diabetes ,asthma and urinary tract infection and Taking any medicine other than folic acid.

Intervention groups

for the treatment of nausea and vomiting of pregnancy , ondanserone is used in one group and metoclopramid is used in the other group.

Main outcome variables

nausea and vomiting (using PUQE checklist); the number of drug doses and the number of days between the admission and discharge.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190528043735N1**

Registration date: **2019-09-30, 1398/07/08**

Registration timing: **retrospective**

Last update: **2019-09-30, 1398/07/08**

Update count: **0**

Registration date

2019-09-30, 1398/07/08

Registrant information

Name

Fatemeh Moradiha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3357 9389

Email address

moradiha.f@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-05, 1398/03/15

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Public title

Comparison of Effectiveness of Ondansetron versus
Metoclopramide in Hyperemesis Gravidarum

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

clinical signs of nausea , vomiting and dehydration
gestational age <16 weeks from the first day of the last
menstruation ketonuria oral intolerance

Exclusion criteria:

gastrointestinal disorders justify nausea and vomiting
multiple pregnancy having certain diseases, such as
diabetes, asthma and urinary tract infection taking any
medicine other than folic acid

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **154**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with coin throwing will be used to
divide patients into two groups of study

Blinding (investigator's opinion)

Double blinded

Blinding description

in this study, the patient and, investigator and analyst of
the data are not prescriptive an any treatment group.In
this double-blind, randomized clinical trial of 154 patients
randomly will be divided into two groups of 77 patients
by coin throwing and accidental drug administration to
patients by a third party(nurse) that does not directly
play a role in conducting the study.Since both drugs are
colorless, patients are not aware of the type of injectable
drug, and only the nurse is aware of the prescription
drug, and the patients are classified into two groups of
one and two.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical
Sciences

Street address

Azadi square, Islamic Republic BLvd, Central Branch
of Zanjan University of Medical Sciences

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2016-05-04, 1395/02/15

Ethics committee reference number

ZUMS.REC.1395.40

Health conditions studied

1

Description of health condition studied

hyperemesis gravidarum

ICD-10 code

O21.1

ICD-10 code description

Hyperemesis gravidarum with metabolic disturbance

Primary outcomes

1

Description

nausea and vomiting

Timepoint

beginning of study and 24 ,48 hours after starting
treatment

Method of measurement

questionnaire PUQE (Pregnancy Unique Quantification of
Emesis)

Secondary outcomes

1

Description

duration of intravenous fluid intake

Timepoint

from start to end of treatment

Method of measurement

review patient medical records and calculate the hours of
intake of fluids

2

Description

number of intravenous doses received

Timepoint
from start to end of treatment

Method of measurement
review patient medical records and calculate the number of doses of medication received

3

Description
length of hospitalization

Timepoint
from start to end of treatment

Method of measurement
review patient medical records and calculate the number of hospita admissions days

Intervention groups

1

Description
Intervention group: one , intravenous ondansetrone 4 milligram every 8 hours, from the beginning of the stay until patients find oral tolerance

Category
Treatment - Drugs

2

Description
Intervention group: two , intravenous metoclopramide 10 milligram every 8 hours, from the beginning of the stay until patients find oral tolerance.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mousavi Hospital Zanjan University of Medical Sciences

Full name of responsible person
Fatemeh Moradiha

Street address
Road Gavazang, Mousavi Hospital

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3418734595

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Email
moradiha.f@gmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
Dr alireza shoghli

Street address
Zanjan, Azadi Boulevard, Zanjan University of Medical Sciences

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Email
shoghli@zums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Zanjan 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
Gonabad University of Medical Sciences

Full name of responsible person
Fatemeh Moradiha

Position
Specialist

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Mosavi hospital, gavazang, zanjan

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is 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

Title and more details about the data/document

A portion of the information, such as information on the main outcome, can be shared.

When the data will become available and for how long

Start one year's period of access after printing the results

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

No data analysis is allowed

From where data/document is obtainable

moradiha.f@gmu.ac.ir

What processes are involved for a request to access data/document

Send an email requesting data receipt

Comments