

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Survey and comparison of the efficacy of Granisetron and Promethazine in control of Hyperemesis Gravidarum

Protocol summary

Summary

Hyperemesis gravidarum (HG) is defined as nausea and vomiting in pregnancy, typically in the first trimester, resulting in dehydration and ketonuria severe enough to justify hospital admission and require intravenous fluid therapy. The purpose of this study is to compare Granisetron and Promethazine in control of Hyperemesis Gravidarum. A total of 120 female patients who will enter the study will get the treatment dose of drugs (Promethazine and Granisetron) in each group. In the first day of treatment, the patients will receive the I.V. form of drugs in order to tolerate the oral diet. After 48 hours, they will be checked for controlling the nausea and vomiting.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108144927N2**

Registration date: **2011-08-16, 1390/05/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-08-16, 1390/05/25

Registrant information

Name

Ashraf Alyasin

Name of organization / entity

Tehran University of Medical Sciences, Dr. Shariati Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2421

Email address

alyasina@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Aburaihan Pharmaceutical Company

Expected recruitment start date

2011-02-01, 1389/11/12

Expected recruitment end date

2012-08-01, 1391/05/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey and comparison of the efficacy of Granisetron and Promethazine in control of Hyperemesis Gravidarum

Public title

Survey and comparison of the efficacy of Granisetron and Promethazine in control of Hyperemesis Gravidarum

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the women in the 20 weeks of pregnancy; referred to gynecology and obstetrics emergency room in Dr.Shariati hospital; inappropriate response to outpatient antiemetic therapies; presenting more than one plus ketonuria in complete analysis of urine; nausea and vomiting score more than 13 (according to the pregnancy unique qualification of emesis) and signing the study written consent. Exclusion criteria: molar pregnancy and sever thyroid or liver disease

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

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

Tehran University of Medical Sciences

Street address

Keshavarz Blvd., Ghods St.

City

Tehran

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

965/130

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

Timepoint

48 hours

Method of measurement

Physical examination

2

Description

Vomiting

Timepoint

48 hours

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Tab Promethazine 25mg qid (I.V. form in the first day of treatment)

Category

Treatment - Drugs

2

Description

Tab Granisetron 1mg bid (I.V. form in the first day of treatment)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Shariati Hospital

Full name of responsible person

Dr. Ashraf Alyasin

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Aburaihan Pharmaceutical Company

Full name of responsible person

Dr. Hashem

Street address

Teharnpars St., Damavand Ave.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Aburaihan Pharmaceutical Company

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**

Dr. Shariati Teaching Hospita

Full name of responsible person

Dr. Ashraf Alyasin

Position

Faculty member

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

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Tehran University of Medical Sciences

Full name of responsible person

Dr.Hassan Torkamandi

Position

Pharmaceutical Care Department Researcher

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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