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
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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
Vomoting
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
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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