

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Demitron and promethazin in treatment of hyperemesis gravidarum

Protocol summary

Summary

To compare the efficacy of demitron and promethazin in treatment of hyperemesis gravidarum 60 pregnant women with clinical hyperemesis gravidarum randomly divided to two groups of 30 and after exclude multiple pregnancy ;nonviable pregnancy; concomitant emetogenic pathology, they received promethazin and demitron in double-blind method, after 48hr severity of nausea and vomiting and adverse drug reactions will be assessed within questionnaire and at the end we compare the treatment efficacy and adverse reactions of 2 drugs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201298862N1**

Registration date: **2012-10-09, 1391/07/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-10-09, 1391/07/18

Registrant information

Name

Yasamin Mehrolhasani

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1281 4283

Email address

881129005@collegian.kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences (vice chancellor for research)

Expected recruitment start date

2011-04-21, 1390/02/01

Expected recruitment end date

2012-09-20, 1391/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Demitron and promethazin in treatment of hyperemesis gravidarum

Public title

Comparison of Demitron and promethazin in treatment of nausea and vomiting in pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: pregnant women with gestation of 20 weeks or less; dehydration due to nausea and vomiting
exclusion criteria: multiple pregnancy; nonviable pregnancy; concomitant emetogenic pathology associated with the symptomatology (hepatitis, gastrointestinal disorder,...)

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**
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

Kerman University of Medical Science(vice chancellor for research)

Street address

Tahmasbabad cross

City

Kerman

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

k/90/229

Health conditions studied

1

Description of health condition studied

nausea and vomiting in pregnancy

ICD-10 code

O21.1

ICD-10 code description

Hyperemesis gravidarum with metabolic disturbance

Primary outcomes

1

Description

nausea and vomiting

Timepoint

48 hours after drug beginning

Method of measurement

questionnaire

Secondary outcomes

1

Description

drug adverse reactions

Timepoint

48 hours after drug beginning

Method of measurement

questionnaire

Intervention groups

1

Description

intervention group:Amp demitron 8mg intramuscular q 8 hour for 48 hours

Category

Treatment - Drugs

2

Description

control group:Amp promethazine 25mg intramuscular q 6hour for 48 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour hospital

Full name of responsible person

Dr yasamin mehrolhasani

Street address

Pajouhesh square, Afzalipour hospital

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences (vice chancellor for research)

Full name of responsible person

Dr Nahid Eftekhari

Street address

Pajouhesh square, Afzalipour hospital

City

Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman University of Medical Sciences (vice chancellor

for research)
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
Kerman University of Medical Sciences
Full name of responsible person
Yasamin Mehrolhasani(MD)
Position
Obstetric and Gynecology resident
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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