

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 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**

**Street address**

Pajouhesh square, Afzalipour hospital

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+98 34 1281 4283

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yasamin\_m@yahoo.com

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**Person responsible for scientific 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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**Contact**

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Kerman University of Medical Sciences

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**Fax**

**Email**

yasamin\_m@yahoo.com

**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*