

Intravenous metoclopramide versus intravenous promethazine for hyperemesis gravidarum: a double-blind, randomised trial

Submission date 17/07/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 31/07/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/04/2010	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
625.10

Study information

Scientific Title

Acronym

PRO-MET Trial

Study objectives

Intravenous metoclopramide is superior to intravenous promethazine as an anti-emetic in hyperemesis gravidarum

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Malaya Medical Centre Medical Ethics Committee approved on the 21st of November 2007 (ref: 625.10)

Study design

Randomised double-blind trial

Primary study design

Interventional

Study type(s)**Health condition(s) or problem(s) studied**

Hyperemesis gravidarum

Interventions

10 mg metoclopramide intravenously versus 25 mg promethazine intravenously at 8 hourly intervals at hospitalisation for hyperemesis gravidarum for up to 24 hours or longer as required.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Metoclopramide, promethazine

Primary outcome(s)

1. Participant well-being over the initial 24-hour period by means of a 10 point visual analogue scale (VAS)
2. Number of vomiting episodes in the initial 24-hour period (participant diary)

Key secondary outcome(s)

1. Nausea score measured using a 10 point VAS at enrolment, 8 , 16 and 24 hours
2. Ketonuria status at the end of 24 study period
3. Additional/ change of anti-emetic required during the study period and during hospitalisation
4. Total doses of intravenous anti-emetic needed during hospitalisation
5. Admission to discharge interval
6. Any adverse events, including side effects profile including symptoms of the following:
 - 6.1. Drowsiness

- 6.2. Inability to sleep
- 6.3. Dry mouth
- 6.4. Dizziness
- 6.5. Diarrhoea
- 6.6. Headache
- 6.7. Palpitations
- 6.8. Uncontrollable movements or muscle spasms
- 6.9. Rash

Completion date

01/03/2010

Eligibility

Key inclusion criteria

- 1. Pregnant women, age limit >17 to 50 years
- 2. Gestation <16 weeks
- 3. First hospitalisation for hyperemesis gravidarum in current pregnancy
- 4. Clinical dehydration with ketonuria on urine dipstick

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

- 1. Multiple gestation
- 2. Established non viable pregnancy
- 3. Allergy to metoclopramide or promethazine
- 4. Pre-existing medical condition which can cause nausea and vomiting if known, for example:
 - 4.1. Concomitant confounders of severity of nausea and vomiting e.g. culture proven symptomatic urinary tract infection, dengue fever
 - 4.2. Gastrointestinal causes of vomiting e.g. gastro-enteritis
 - 4.3. Medical causes of vomiting e.g. diabetic ketoacidosis

Date of first enrolment

01/09/2008

Date of final enrolment

01/03/2010

Locations

Countries of recruitment

Malaysia

Study participating centre

Department of Obstetrics and Gynaecology

Kuala Lumpur

Malaysia

50603

Sponsor information**Organisation**

University of Malaya (Malaysia)

ROR

<https://ror.org/00rzspn62>

Funder(s)**Funder type**

University/education

Funder Name

University of Malaya (Malaysia) (Grant ref: PJP/FS227/2008B)

Alternative Name(s)

University of Malaya, University Malaya, Malayan University, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Malaysia

Funder Name

CCM Duopharma Malaysia Biotech Berhad (Malaysia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2010		Yes	No