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

Submission date	Recruitment status	[X] Prospectively registered
17/07/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/07/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/04/2010	Pregnancy and Childbirth	

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)

Primary study design
Interventional

Study design
Randomised double-blind trial

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-exiting 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