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Metoclopramide versus prochlorperazine for hyperemesis gravidarum

Submission date 13/11/2009	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 17/02/2011	**Overall study status** Completed	
Last Edited 17/02/2011	**Condition category** 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
732.20

Study information

Scientific Title
Metoclopramide versus prochlorperazine for hyperemesis gravidarum: a double blind randomised trial

Acronym
MetPro Trial

Study objectives
Prochlorperazine is as effective as metoclopramide for hyperemesis gravidarum.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Malaya Medical Centre Medical Ethics Committee approved on the 31st July 2009

Study design
Double blind randomised trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hyperemesis gravidarum

Interventions
Metoclopramide (10 mg) or prochlorperazine (12.5 mg) intravenously 8-hourly for 24 hours.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Prochlorperazine, metoclopramide

Primary outcome(s)
1. Satisfaction score at 24 hours using a self-administered 10 point visual numerical rating scale (VNRS)
2. Frequency of vomiting during the 24 hours study period

Key secondary outcome(s))
1. Nausea scores measured using a 10 point VNRS at enrolment, 8 hours, 16 hours and 24 hours
2. Ketonuria status at the end of study period
3. Addition or change of anti-emetic required during the study period
4. Admission to discharge interval
5. Time to discontinuation of IV fluids
6. Time to discontinuation of IV anti-emetics
7. Any adverse events
8. Self administered side effects profile at end of study period - symptoms of:

8.1. Drowsiness
8.2. Inability to sleep
8.3. Dry mouth
8.4. Dizziness
8.5. Diarrhoea
8.6. Headache
8.7. Palpitations
8.8. Uncontrollable movements or muscle spasms
8.9. Rash

Completion date
05/11/2010

Eligibility

Key inclusion criteria
1. Females aged over 16 years
2. First hospitalisation for hypermesis gravidarum in current pregnancy
3. Gestation less than 20 weeks
4. Clinically dehydrated with ketonuria

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Multiple gestation
2. Proven non viable pregnancy
3. Pre-existing medical condition that can cause nausea and vomiting, e.g.:
3.1. Concomitant confounders of severity of nausea and vomiting, e.g., culture proven symptomatic urinary tract infection, dengue fever
3.2. Gastrointestinal causes of vomiting, e.g., gastro-enteritis
3.3. Medical causes of vomiting e.g. diabetic ketoacidosis
3.4. Allergies to metoclopramide or prochlorperazine

Date of first enrolment
06/11/2009

Date of final enrolment
05/11/2010

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)

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

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes