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# Metoclopramide versus prochlorperazine for hyperemesis gravidarum

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof Peng Chiong Tan

**Contact details**
Department of Obstetrics and Gynaecology
Faculty of Medicine
University of Malaya
Lembah Pantai
Kuala Lumpur
Malaysia
50603

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

### 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 measure
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

### Secondary outcome measures
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

### Overall study start date
06/11/2009

### 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

### Age group
Adult

### Sex
Female

### Target number of participants

At least 128 women

### 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)

### Sponsor details
University of Malaya Medical Centre
Department of Obstetrics and Gynaecology
Lembah Pantai
Kuala Lumpur
Malaysia
50603

### Sponsor type
University/education

**Website**
http://www.um.edu.my/

**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, UM

**Funding Body Type**
Government organisation

**Funding Body Subtype**
Universities (academic only)

**Location**
Malaysia

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration