

Metoclopramide versus prochlorperazine for hyperemesis gravidarum

Submission date 13/11/2009	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 17/02/2011	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 17/02/2011	Condition category Pregnancy and Childbirth	☐ Individual participant data
		☐ 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

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

Primary study design

Interventional

Study design

Double blind randomised trial

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. Ketouria 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 hyperemesis 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