

Metoclopramide versus prochlorperazine for hyperemesis gravidarum

Submission date 13/11/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 17/02/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 17/02/2011	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 hyperemesis 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