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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

Contact name
Prof Peng Chiong Tan

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

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design
Randomised double-blind trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

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
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 measure
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)

Secondary outcome measures
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

Overall study start date
01/09/2008

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

Age group
Adult

Sex
Female

Target number of participants
128

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)

Sponsor details
Lembah Pantai
Kuala Lumpur
Malaysia
50603

Sponsor type
University/education

Website
http://um.edu.my

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, 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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2010		Yes	No