

Ondansetron versus metoclopramide for hyperemesis gravidarum

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|----------------------------------------|-------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| Submission date 30/04/2012 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 08/05/2012 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 12/05/2014 | Condition category Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims:

Hyperemesis gravidarum (HG) is a pregnancy related condition characterized by severe nausea and vomiting, weight loss and electrolyte disturbance requiring a stay in hospital for treatment.

Metoclopramide is a common first line medication used in the treatment of HG aiming to reduce nausea and vomiting. Ondansetron is a similar drug. Ondansetron is more effective than metoclopramide in other settings e.g. during chemotherapy and after surgery. The experience with ondansetron in the treatment of HG is not as large as that with metoclopramide but available data suggest that both metoclopramide and ondansetron do not cause problems for the baby.

It is not known in context of treatment for HG, which agent, metoclopramide or ondansetron is more effective or has fewer side effects.

We are doing a study comparing metoclopramide with ondansetron during the initial 24 hours of inpatient treatment for HG. Treatment after this 24 hour study period will revert to the standard treatment for HG.

The aim is to investigate whether ondansetron is more effective than metoclopramide in the initial treatment of HG in producing greater well being, reducing vomiting and nausea or has less side effects.

Who can participate?

Women hospitalised for the first time in the current pregnancy due to uncomplicated HG who is aged 18 years and above and not more than 16 weeks pregnant can take part.

What does the study involve?

All women hospitalised with HG in our centre receive an anti emetic medication intravenously in their initial treatment. You will be randomly assigned to receive either metoclopramide or ondansetron given intravenously every 8 hours for 24 hours. You will need to fill in score sheets for well being, nausea and vomiting during the 24 hour study period

Randomisation means that you will have an equal chance of getting either medicine but the allocation will be decided by a chance process. Neither your doctor nor you will be informed which medicine you will receive (this process called blinding is to reduce bias). The nature of the

medicine received by you will be released to your doctor if needed. Your doctor can still change, stop or add your medication.

What are the possible benefits and risks of participating?

Both ondansetron and metoclopramide are in common use for the treatment of HG. No major risk is anticipated. However, you may be allocated to treatment that may subsequently be shown by this study to be less effective and/or has more side effects.

Where is the study run from?

Gynaecology Ward, University Malaya Medical Centre, Kuala Lumpur, Malaysia.

When is study starting and how long is it expected to run for?

November 2011 to May 2013

Who is funding the study?

Department of Obstetrics and Gynaecology, University Malaya Medical Centre

Who is the main contact?

Prof Siti Zawiah Omar

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Contact information

Type(s)

Scientific

Contact name

Prof Siti Zawiah Omar

Contact details

University of Malaya

Department of Obstetrics and Gynaecology

Faculty of Medicine

Lembah Pantai

Kuala Lumpur

Malaysia

50603

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

871.2

Study information

Scientific Title

Ondansetron versus metoclopramide For hyperemesis gravidarum: a randomized trial

Study objectives

Ondansetron compared to metoclopramide is a more effective anti emetic agent when used in the initial inpatient management of hyperemesis gravidarum with anticipated higher sense of well being and reduced frequency of vomiting at the end of 24 hour study period.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University Malaya Medical Centre Medical Ethics Committee, 24 August 2011, ref: 871.2

Study design

Comparative groups in 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 - excessive vomiting in pregnancy

Interventions

Intervention: Participants will receive either 4mg ondansetron every 8 hours or 10mg metoclopramide every 8 hours for 24 hours intravenously. Participants will also receive standard intravenous rehydration. After 24 hours, open label standard treatment for hyperemesis gravidarum applies.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Visual numerical rating scale score of overall wellbeing at 24 hours
2. Frequency of vomiting in the first 24 hours

Secondary outcome measures

1. Visual numerical rating scale score for nausea at enrolment, 8,16 and 24 hours
2. Adverse symptom profile
3. Ketonuria status at the end of 24 hour period
4. Treatment curtailment and changes
5. Total antiemetic drug dose
6. Length of hospital stay

Overall study start date

07/11/2012

Completion date

06/05/2013

Eligibility

Key inclusion criteria

1. First hospitalization for hyperemesis gravidarum (severe nausea and vomiting of pregnancy)
2. Gestation 16 weeks or less
3. Clinical dehydration with ketonuria on dipstick
4. Women in their first hospitalisation for presumed hyperemesis gravidarum

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

At least 128 women

Key exclusion criteria

1. Multiple gestation
2. Established non viable pregnancy
3. Pre-existing medical condition which can cause nausea and vomiting if known, for example:
 - 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. Allergy to metoclopramide or ondansetron

Date of first enrolment

07/11/2012

Date of final enrolment

06/05/2013

Locations

Countries of recruitment

Malaysia

Study participating centre

University of Malaya

Kuala Lumpur

Malaysia

50603

Sponsor information

Organisation

University of Malaya (Malaysia)

Sponsor details

Faculty of Medicine

Department of Obstetrics and Gynaecology

Lembah Pantai

Kuala Lumpur

Malaysia

50603

Sponsor type

University/education

Website

http://medicine.um.edu.my/?modul=DEPARTMENTS&pilihan=Obstetrics_and_Gynecology

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

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/06/2014 | | Yes | No |