Oral Nifedipine versus Intravenous Labetalol hydrochloride for acute blood pressure control in Hypertensive Emergencies of Pregnancy

Submission date Recruitment status [] Prospectively registered 01/02/2011 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 17/03/2011 Completed [X] Results [] Individual participant data Last Edited Condition category Pregnancy and Childbirth 31/01/2012

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Rahmah Saaid

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

738.15

Study information

Scientific Title

Oral nifedipine versus intravenous labetalol hydrochloride for acute blood pressure control in hypertensive emergencies of pregnancy: a double blind randomised clinical trial

Acronym

ONILHEP

Study objectives

Oral nifedipine has a more rapid effect on blood pressure in a hypertensive emergency of pregnancy compared to intravenous labetalol hydrochloride.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Malaya Medical Centre Medical Ethics Committee approved on the 8th September 2009 (ref: 738.15)

Study design

Double blind randomised clinical 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

Severe hypertension of pregnancy

Interventions

Randomisation to regimen (A) nifedipine 10 mg tablet orally and intravenous placebo saline injection (up to 5 doses) or regimen (B) intravenous labetalol injection (at escalating dose regimen of 20 mg, 40 mg, 80 mg 80 mg and 80 mg) and a placebo tablet, repeated every 15 minutes until target blood pressure less than or equal to 150/100 mmHg is achieved.

Crossover treatment is carried out if the target blood pressure is not achieved after completion of the allocated regimen. Total duration of treatment is up to 2.5 hours and maximum follow up is at hospital discharge after delivery of the baby.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Nifedipine, labetalol hydrochloride

Primary outcome measure

The time taken to achieve target systolic blood pressure less than or equal to 150 mmHg and diastolic blood pressure less than or equal to 100 mmHg, measured at no later than 3 hours after commencement of treatment

Secondary outcome measures

- 1. Number of drug doses required to achieve target pressure less than or equal to 150/100 mmHg
- 2. Blood pressure profile during study period (a minimum of 1 hour from study drug administration or time taken to achieve target blood pressure whichever is the longer)
- 3. Maternal pulse profile during study period
- 4. Cardiotocogram abnormality
- 5. Maternal hypotension (blood pressure less than 90/60 mmHg)
- 6. Side effects profile by questionnaire at the end of the study period
- 7. Retreatment for hypertensive crises in 2 weeks following randomisation

Measurements not later than at hospital discharge following delivery of the baby.

Overall study start date

02/01/2010

Completion date

18/10/2010

Eligibility

Key inclusion criteria

- 1. Sustained severe hypertension defined as systolic blood pressure of greater than or equal to 160 mmHg and/or diastolic blood pressure greater than or equal to 110 mmHg on at least two occasions in the last 4 hours, at least 30 minutes apart. The latest blood pressure reading must fulfil the criteria of severe hypertension.
- 2. Medical decision to rapidly control blood pressure
- 3. Greater than or equal to 24 weeks gestation
- 4. Viable singleton foetus with acceptable cardiotocography (CTG)
- 5. Maternal heart rate greater than or equal to 60 bpm and less than or equal to 120 bpm
- 6. Aged 19 40 years, all pregnant females

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

50 in total

Key exclusion criteria

- 1. Maternal history of cardiac arrhythmia
- 2. Heart failure
- 3. Asthma
- 4. Allergy or contraindication to either nifedipine or labetalol hydrochloride
- 5. Antihypertensive drug treatment in the last 72 hours

Date of first enrolment

02/01/2010

Date of final enrolment

18/10/2010

Locations

Countries of recruitment

Malaysia

Study participating centre Department of Obstetrics and Gynaecology

Kuala Lumpur Malaysia 50603

Sponsor information

Organisation

University of Malaya Medical Centre (Malaysia)

Sponsor details

Department of Obstetrics and Gynaecology Lembah Pantai Kuala Lumpur Malaysia 50603

Sponsor type

University/education

Website

http://www.ummc.edu.my/

ROR

https://ror.org/00vkrxq08

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 typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results articleresults01/01/2012YesNo