

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

Submission date 01/02/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 17/03/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 31/01/2012	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

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, 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2012		Yes	No