ISRCTN78140744 https://doi.org/10.1186/ISRCTN78140744

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

Registration date
17/03/2011

Overall study status
Completed

Last Edited
31/01/2012

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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