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Hypitat: Pregnancy-induced hypertension and pre-eclampsia after 36 weeks: induction of labour versus expectant monitoring. A comparison of maternal and neonatal outcome, maternal quality of life and costs.

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
19/09/2012

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] 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
NTR300

Study information

Scientific Title

Acronym
Hypitat (Hypertension and Preeclampsia Intervention Trial at Term)

Study objectives
Equivalence between maternal and neonatal outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Medical Ethical Committee of the University Medical Centre of Leiden (ref: p04.210)

Study design
Multicentre randomised active controlled parallel group 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
Pre-eclampsia, pregnancy induced hypertension

Interventions
In the intervention group, patients get an induction of labour within 24 hours after randomisation. Patients with a cervix that is judged to be 'ripe' at vaginal examination (bishop

score greater than 6), labour will be induced with amniotomy and augmentation with oxytocin. In case the cervix is judged to be 'unripe' (bishop score less than 6), cervical ripening will be stimulated with use of intracervical or intravaginal prostaglandines according to the local protocol.

In the expectant group, patients will be monitored until the onset of spontaneous delivery. In this group intervention is recommended in case the foetal or maternal condition does not justify expectant management anymore.

As of 06/01/2009, this record was updated to show the completed status based on the participant inclusion completion date of April 2008. The previous anticipated end date of this trial was 01/02/2009.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary outcome measure will be maternal mortality or severe maternal morbidity. Severe maternal morbidity will be defined as diastolic BP greater than 110 mmHg, major postpartum haemorrhage, eclampsia, HELLP syndrome or abruptio placenta.

Previous primary outcome measures (as of 22/08/2007):
Maternal and neonatal outcome, quality of maternal life.

Secondary outcome measures
Secondary outcomes will be neonatal mortality or neonatal morbidity, instrumental delivery rate, severe maternal quality of life and quality of recovery and costs.

Previous secondary outcome measures (as of 22/08/2007):
Economic analysis

Overall study start date
01/02/2006

Completion date
01/04/2008

Eligibility

Key inclusion criteria
Current inclusion criteria (as of 22/08/2007):
1. Pregnant women with gestational age 36 0/7 weeks until 41 0/7 weeks
2. Blood pressure greater than 140/95 mmHg in women with pregnancy induced hypertension
3. Blood pressure greater than 140/90 mmHg combined with proteinuria (greater than 300 mg /24 hours) in women with preeclampsia

Previous inclusion criteria:
1. Pregnant women with gestational age 36 0/7 wks until 41 0/7 wks

2. Blood pressure greater than 140/95 mmHg. Eventually combined with proteinuria (greater than 300 mg/24 hour)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
250 (750 as of 22/08/2007)

Key exclusion criteria
1. Treated hypertension before pregnancy
2. Diabetes mellitus
3. Renal disease and previous caesarean section
4. HELLP syndrome
5. Oluguria
6. Cerebral or visual disturbances
7. Pulmonary oedema or cyanosis
8. Non-vertex position

Date of first enrolment
01/02/2006

Date of final enrolment
01/04/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Groningen
Groningen
Netherlands
9700 RB

Sponsor information

Organisation

The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Sponsor details
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Sponsor type
Research organisation

Website
http://www.zonmw.nl/

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

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?
Protocol article	methods of valuation/preference protocol:	04/07/2007		Yes	No
Protocol article	trial protocol:	27/07/2007		Yes	No

Results article	results	19/09/2009	Yes	No
Results article	results	01/12/2010	Yes	No
Results article	results	01/12/2011	Yes	No
Results article	results	01/12/2011	Yes	No
Results article	results	01/12/2011	Yes	No
Results article	results	01/08/2012	Yes	No