HYPITAT-II

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29619

Source
NTR

Brief title
HYPITAT-II

Health condition

Preeclampsia, gestational hypertension, induction of labour

Preeclampsie, zwangerschaps hypertensie, inleiden van de baring

Sponsors and support

Primary sponsor: Dutch consortium for studies in obstetrics, gynaecology, fertility, neonatology, gynaecological oncology, and urogynaecology.
Source(s) of monetary or material Support: ZonMw Grant application 80-82310-97-10038

Intervention

Outcome measures

Primary outcome

Primary outcome measures are for the mother a composite endpoint of maternal mortality, maternal complications (eclampsia, HELLP syndrome, pulmonary edema), thrombo-embolic disease and placental abruption.

The neonatal primary outcome measure is respiratory distress syndrome (RDS).

Secondary outcome

Secondary maternal outcomes will be caesarean section rate, instrumental vaginal delivery rate, maternal quality of life and quality of recovery and costs.

Secondary neonatal outcome will be neonatal morbidity defined as neonatal infection or sepsis, intravenous therapy needed hypoglycaemia, wet lung syndrome, meconium aspiration syndrome, pneumothorax and/or pneumomediastinum, periventricular leucomalacia, convulsions and other neurological abnormalities necrotising enterocolitis (NEC), intraventricular haemorrhage (IVH) or asphyxia. Adverse neonatal outcome will be defined as a 5-minute Apgar score below 7 and an umbilical artery pH below 7.05 or admission to neonatal intensive care.

Study description

Background summary

Gestational hypertension, deteriorating chronic hypertension and preeclampsia between 34 and 37 weeks: induction of labour versus expectant monitoring. A comparison of maternal and neonatal outcome, maternal quality of life and costs.

Study design:

Multicentre randomised placebo-controlled trial. The study will be performed within a consortium nationwide including ten perinatal centres, which are collaborating in several studies.

Study population:

Women with a gestational age between 34+0 and 37+0 weeks who are diagnosed with gestational hypertension, deteriorating chronic hypertension or preeclampsia.

Study objective

We hypothesize that induction of labour in patients with gestational hypertension, deteriorating chronic hypertension or preeclampsia between 34 and 37 weeks reduce the maternal morbidity but might increase the RDS rate in neonates, compared to expectant monitoring.

Study design

1. Maternal morbidity: short term outcome after delivery;

2. Maternal quality of life: 6 months;

3. Respiratory distress syndrome: neonatal period.

Intervention

Patients will be randomly allocated to induction of labour or to expectant management until 37 weeks gestation.

Contacts

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Eligibility criteria

Inclusion criteria

1. Maternal age > 18 years;

2. Gestational age 34+0 - 37+0;

3. Informed consent.

Diagnosed with gestational hypertension:

1. 100 mmHg ≤ diastolic blood pressure < 110 mmHg;

2. Patients (>110mmHg) who reach a stable diastolic blood pressure of ≤ 110 mmHg after medication.

Patients with chronic hypertension (diagnosed before 20 weeks of pregnancy):

1. Who develop preeclampsia between 34 and 37 weeks of pregnancy;

2. Who have the need for additional medication after 34 weeks.

Diagnosed with pre-eclampsia:

1. Diastolic blood pressure ≥ 90 mmHg ¡Ü (at two occasions at least six hours apart);

2. 0,3 g ≤ proteinuria < 5 g or 2 + proteinuria with dipstick or EKR > 30.

Exclusion criteria

1. Diastolic blood pressure equal/greater than 110 mmHg despite medication;

2. Systolic blood pressure equal/greater than 170 mmHg despite medication;

3. Proteinuria equal/greater than 5 g/L;

4. Renal disease;

5. Heart disease;

6. Seropositive for HIV;

7. Eclampsia;

8. HELLP syndrome;

9. Pulmonary edema or cyanosis;

10. Oliguria less than 500 mL in 24 hours;

11. Non-reassuring fetal heart rate;

12. Ruptured membranes;

13. Fetal abnormalities including abnormal karyotype;

14. Severe preeclamptic complaints, such as frontal headache.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2009
Enrollment:	680
Type:	Actual

Ethics review

Positive opinion

Date:	02-05-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1691
NTR-old	NTR1792
Other	ABR : 24278
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A