

HYPITAT-II

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29619

Bron

NTR

Verkorte titel

HYPITAT-II

Aandoening

Preeclampsia, gestational hypertension, induction of labour

Preeclampsie, zwangerschaps hypertensie, inleiden van de baring

Ondersteuning

Primaire sponsor: Dutch consortium for studies in obstetrics, gynaecology, fertility, neonatology, gynaecological oncology, and urogynaecology.

Overige ondersteuning: ZonMw Grant application 80-82310-97-10038

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

1. Maternal morbidity: short term outcome after delivery;
2. Maternal quality of life: 6 months;
3. Respiratory distress syndrome: neonatal period.

Onderzoeksproduct en/of interventie

Patients will be randomly allocated to induction of labour or to expectant management until

37 weeks gestation.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Maternal age > 18 years;
2. Gestational age 34+0 - 37+0;
3. Informed consent.

Diagnosed with gestational hypertension:

1. $100 \text{ mmHg} \leq \text{diastolic blood pressure} < 110 \text{ mmHg}$;
2. Patients ($>110 \text{ mmHg}$) who reach a stable diastolic blood pressure of $\leq 110 \text{ mmHg}$ 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 (at two occasions at least six hours apart);
2. $0,3 \text{ g} \leq \text{proteinuria} < 5 \text{ g}$ or $2 +$ proteinuria with dipstick or EKR > 30 .

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2009
Aantal proefpersonen:	680
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	02-05-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A