HYpertension and Preeclampsia Intervention Trial in the Almost Term Patient (HYPITAT-2)

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In view of the outcome of the HYPITAT study, one can raise the question how women with preeclampsia or severe hypertension between 34 and 37 weeks of gestation should be managed. Induction of labour might prevent maternal complications. However,...

Ethical review	-
Status	Recruitment stopped
Health condition type	Maternal complications of pregnancy
Study type	Interventional

Summary

ID

NL-OMON38165

Source
ToetsingOnline

Brief title
HYPITAT-2

Condition

- Maternal complications of pregnancy

Synonym
pre-eclampsia, toxemia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMw

Intervention

Keyword: expectant, induction, preeclampsia, preterm

Outcome measures

Primary outcome

The primary outcome measure will be severe maternal and neonatal morbidity, which can be complicated by maternal and neonatal mortality in rare cases. Severe maternal morbidity will be defined as; eclampsia, HELLP syndrome, pulmonary edema, trombo-embolic disease and/or placental abruption, multi-organ-failure, admission to an intensive care unit. Severe neonatal morbidity will be defined as IRDS.

Secondary outcome

Secondary outcomes will be neonatal morbidity due to prematurity, caesarean section rate, instrumental vaginal delivery rate, maternal quality of life and costs.

Study description

Background summary

10% to 15% of all pregnancies are complicated by hypertensive disorders, i.e. gestational hypertension or preeclampsia (19.000 women per year in The Netherlands). The large majority of these cases occur beyond 34 weeks of pregnancy. There is no causal treatment but termination of pregnancy. In case of pre-term pregnancies complicated by hypertension, conservative management is advocated to as long as the risks for the mother are acceptable.
Recently, our group evaluated whether a policy of induction of labour in women with mild preeclampsia or gestational hypertension was superior to a policy of expectant management. We found that induction of labour reduced the number of complications, such as severe hypertension, whereas there was no increase in caesarean sections. Based on these data, we recommended induction of labour in

women with mild preeclampsia or hypertension at term.

Study objective

In view of the outcome of the HYPITAT study, one can raise the question how women with preeclampsia or severe hypertension between 34 and 37 weeks of gestation should be managed. Induction of labour might prevent maternal complications. However, late preterm births are common and associated with significantly increased neonatal mortality and morbidity compared with births at 39 weeks. We aim to make a comparison of maternal and neonatal outcome, maternal quality of life and costs.

Study design

Multicentre randomised controlled clinical trial.

Intervention

Induction of labour, if necessary preceded by artificial cervical ripening versus expectant monitoring.

Study burden and risks

We think that the estimated burden and risk for the patient is low, while a delivery will happen anyway in short time notice. The exact moment though will be influenced.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients 18 years of age or older which have gestational hypertension or pre-eclampsia at a gestational age between 34+0 and 37+0 weeks of gestation. A diagnosis of pregnancy induced hypertension is made in case the diastolic blood pressure is above 100 mmHg at two occasions at least six hours apart in a woman who was normotensive until at least 20 weeks of gestation. A diagnosis of preeclampsia is made in case the diastolic blood pressure is above 90 mmHg and there exists a proteinuria > 300 mg total protein in a 24 hour urine collection.
inclusion criteria:
- Maternal age * 18 years
- Gestational hypertension defined as:
o 100 mmHg < diastolic blood pressure < 110 mmHg
o at two occasions at least six hours apart
- Pre-eclampsia defined as:
o 90 mmHg * diastolic blood pressure < 110 mmHg
o at two occasions at least six hours apart
o 0,3 g * proteinuria < 10 g
o proteinuria > 300 mg total protein in an 24 hour urine collection
- Gestational age between 34+0 and 37+0 weeks
- Informed consent
- Women with singleton or multiple pregnancy
- Women with a child in cephalic or breech presentation

Exclusion criteria

* Diastolic blood pressure * 110 mmHg despite medication
* Systolic blood pressure * 170 mmHg despite medication
* Renal disease

* Heart disease
* Seropositive for HIV
* HELLP syndrome
* Pulmonary edema or cyanosis
* Proteinuria * 5 g/L
* Oliguria < 500 mL in 24 hours
* Non-reassuring foetal heart rate
* Foetal abnormalities including abnormal karyotype.
* Severe preeclamptic complaints, such as frontal headache
* Ruptured membranes

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2009
Enrollment:	680
Type:	Actual

Ethics review

Approved WMO Date:	18-02-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT1792
CCMO	NL24278.018.08