The CHIPS Trial (Control of Hypertension In Pregnancy Study)

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For pregnant women with non-severe non-proteinuric maternal hypertension at 14-33 weeks, will *less tight* control (target dBP of 100mmHg) vs. *tight* control (target dBP of 85mmHg) increase or decrease the likelihood of pregnancy loss or neonatal...

Ethical review	Approved WMO
Status	Pending
Health condition type	Maternal complications of pregnancy
Study type	Interventional

Summary

ID

NL-OMON35551

Source
ToetsingOnline

Brief title
CHIPS

Condition

- Maternal complications of pregnancy
- Vascular hypertensive disorders

Synonym
chronic hypertension, gestational hypertension

Research involving
Human

Sponsors and support

Primary sponsor: THE UNIVERSITY OF BRITISH COLUMBIA, Departments of Obstetrics and Gynaecology & Medicine
Source(s) of monetary or material Support: De studie wordt gefinancierd door de Canadian Institute for Health Research (CIHR)

Intervention

Keyword: hypertension, medication, outcome, Pregnancy

Outcome measures

Primary outcome

Pregnancy loss (miscarriage, pregnancy termination, stillbirth, or neonatal death) or NICU admission for >48hr in the first 28 days of life or prior to primary hospital discharge, whichever is later.

Secondary outcome

Secondary: One/more serious maternal complication(s) until six weeks postpartum (Section 2.8.2, Table 3).

Study description

Background summary

Women with non-severe non-proteinuric pre-existing hypertension (1% of deliveries) or gestational hypertension remote from term (2-3%) represent a high-risk group from both maternal and perinatal perspectives. It is still unclear how best to manage the non-severe hypertension in order to do more good than harm. The placenta does not autoregulate blood flow, so allowing blood pressure (BP) to be higher may improve uteroplacental perfusion, fetal growth, and ultimately, neonatal well-being. Based on our meta-analyses of RCTs, arguments can be made both for and against *less tight* control of BP (allowing for higher BP levels). *Less tight* control may decrease the risk of small for gestational age (SGA) infants, but may also increase the risk of (transient) severe maternal hypertension, antenatal hospitalisation, and proteinuria at delivery. However, there is insufficient evidence on which to base clinical decisions because of reporting bias and between-trial heterogeneity in outcome. Guidelines are founded mainly on expert opinion. Our national survey found that Canadian obstetricians are divided on these issues. The CIHR-funded CHIPS Pilot Trial confirmed the importance and feasibility of a definitive RCT. Clinicians complied with the interventions and women were satisfied with their care. *Less tight* (vs. *tight*) control resulted in higher dBP, and a more favourable effect on perinatal outcomes. We need a definitive RCT to inform clinical

decision-making. Therefore, we propose the CHIPS Trial.

Study objective

For pregnant women with non-severe non-proteinuric maternal hypertension at 14-33 weeks, will *less tight* control (target dBP of 100mmHg) vs. *tight* control (target dBP of 85mmHg) increase or decrease the likelihood of pregnancy loss or neonatal intensive care unit (NICU) admission for more than 48hr?

Study design

The CHIPS Trial is an international multicentre RCT that will recruit 1,028 women (514/group) from 50 tertiary and community centres over 4 years. Eligible women will be randomised centrally to either *less tight* control (aiming for dBP of 100mmHg) or *tight* control (aiming for dBP of 85mmHg) of their hypertension. Randomisation will be stratified by centre and type of hypertension (pre-existing or gestational).
The primary outcome will be compared between groups using adjusted logistic regression (alpha of 0.046, two-sided). Two interim analyses are planned after primary outcome data are available for 1/3 and 2/3 of enrolled women; our independent Data Safety Monitoring Board will use $p<0.0002$ and $p<0.012$, two-tailed, as guidelines for considering early termination of the trial at the first and second interim analyses, respectively.
Follow-up: Outcome data will be collected during the woman*s (and baby*s) hospital stay for birth (or loss). Women will be contacted at approximately six weeks after delivery (or loss) to enquire about satisfaction with care, disruption of home or family life, any major maternal/neonatal morbidity following hospital discharge, and views about BP management.

Intervention

In the *less tight* control group, if dBP is * 105mmHg, then antihypertensive medication must be started or increased in dose. In the *tight* control group, if dBP is * 80mmHg, then antihypertensive medication must be decreased in dose or discontinued. Both groups: Centres will provide their usual care. Data will be collected on potential co-interventions (e.g., hospitalisation, bed-rest). Compliance (dBP and antihypertensive dose) will be assessed at two weeks (± 7 days) after randomisation.

Study burden and risks

Patients are subjected to either treatment stategy, both of which are standard practice in the Netherlands. In that sense there is no additional burden. however, blood pressure will be measured according to guidelines. This will take a few minutes more time, but will actually result in improvement of care, because standard practice is suboptimal measurement of blood pressure.

Additional burden is in the diary that is kept by the patient to record all visitis to professionals involved in the prenatal care; also patients will be called several times to keep track of the events in pregnancy.

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

pre-existing/gestational hypertension; office dBP 90-105mmHg (or dBP 85-105mmHg if on antihypertensive medication); live fetus; and 14-33+6 weeks.

Exclusion criteria

Severe systolic hypertension; proteinuria; contraindication to either arm of trial or to prolongation of pregnancy; ACE inhibitor use in pregnancy; known multiple gestation or lethal/major fetal anomaly; plan to terminate pregnancy; or prior participation in CHIPS.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2009
Enrollment:	220
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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
ISRCTN	ISRCTN71416914
CCMO	NL26191.018.08