

CHIPS (Control of Hypertension in Pregnancy Study): a pilot trial

Submission date 05/11/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/11/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/11/2009	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Laura Magee

Contact details
790 Bay Street., 7th Floor
Toronto
Canada
M5G 1N8

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00187395

Protocol serial number
N/A

Study information

Scientific Title

Acronym

Study objectives

To determine whether less tight control of mild-moderate nonproteinuric maternal hypertension, aiming for a diastolic Blood Pressure (dBP) of 100 mmHg, can decrease the risks of adverse perinatal outcome without increasing maternal risk compared with tight control, aiming for a dBP of 85 mmHg.

This is the pilot study for the main randomised trial registered under ISRCTN71416914.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Trial has been approved by the University of British Columbia Research Ethics Board.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mild-Moderate hypertension particularly of the short-term period of pregnancy.

Interventions

Women will be randomised to either a 'less tight' group aiming for a diastolic Blood Pressure (dBP) of 100 mmHg of maternal hypertension or a 'tight' group aiming for a diastolic BP of 85 mmHg of maternal hypertension.

'Less tight' control: a target dBP of 100 mmHg

1. If dBP is 95 - 99 mmHg, consideration should be given to decreasing the dose or stopping antihypertensive therapy among women already on treatment, and therapy should not be started among women on no treatment.
2. If dBP is less than 95 mmHg, antihypertensive therapy should definitely be decreased in dose or stopped among women already on treatment, and should not be started among women on no treatment.
3. If dBP is 101 - 105 mmHg, consideration should be given to starting antihypertensive therapy or increasing the dose of existing medication.
4. If dBP is greater than 105 mmHg, antihypertensive therapy should definitely be started or existing medication increased in dose.

'Tight' control: a target dBP of 85 mmHg

1. If dBP is 80 - 84 mmHg, consideration should be given to stopping or decreasing the dose of antihypertensive therapy among women already on treatment, and therapy should not be started among women already on treatment.
2. If dBP is less than 80 mmHg, antihypertensive therapy should definitely be decreased in dose or stopped among women already on treatment, and should not be started among women on no

treatment.

3. If dBP is 86 - 90 mmHg, consideration should be given to starting or increasing the dose of existing antihypertensive medication.

4. If dBP is greater than 90 mmHg, antihypertensive therapy should definitely be started or existing medication increased in dose.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Mean dBP at 28, 32 and 36 weeks gestation

2. One/more serious perinatal complications or birth weight less than third centile

Key secondary outcome(s)

1. Clinician compliance with treatment protocols

2. Womens satisfaction with care

3. One/more serious maternal complications

Other outcomes:

1. Very severe hypertension

2. Pre-eclampsia

Completion date

31/12/2004

Eligibility

Key inclusion criteria

Women 18 - 50 years old with mild to moderate non-proteinuric pre-existing or gestational hypertension that presents at 20-33+6 weeks gestation.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. dBP consistently less than 85 mmHg by home BP monitoring
2. Severe systolic hypertension
3. Proteinuria
4. Contraindication to either arm of the trial or to prolongation of pregnancy
5. Known lethal/major fetal anomaly

Date of first enrolment

01/03/2003

Date of final enrolment

31/12/2004

Locations

Countries of recruitment

Canada

Study participating centre

790 Bay Street., 7th Floor

Toronto

Canada

M5G 1N8

Sponsor information

Organisation

University of Toronto Maternal, Infant and Reproductive Health Research Unit (Canada)

ROR

<https://ror.org/03dbr7087>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-59755)

Results and Publications

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?
Results article	Results:	01/06/2007		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes