

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

<b>Submission date</b> 05/11/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/11/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/11/2009	<b>Condition category</b> 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

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## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT00187395

## Study information

**Scientific Title**

**Acronym**  
CHIPS

**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?
<a href="#">Results article</a>	Results:	01/06/2007		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes