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

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 05/11/2003 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 28/11/2003 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 19/11/2009 | Pregnancy and Childbirth | |

**Plain English summary of protocol**
Not provided at time of registration

**Study website**
http://www.utoronto.ca/miru/chips/res_summ.htm

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Laura Magee

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

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**
NCT00187395

**Secondary identifying numbers**
N/A

# 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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet

## 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 dialstolic 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 measure
1. Mean dBP at 28, 32 and 36 weeks gestation
2. One/more serious perinatal complications or birth weight less than third centile

### Secondary outcome measures
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

### Overall study start date
01/03/2003

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Female

### Target number of participants
132 women (66/group)

### 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)

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

### Sponsor type
University/education

### Website
http://www.utoronto.ca/

### 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

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### 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 |