ISRCTN57277508 https://doi.org/10.1186/ISRCTN57277508

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