ISRCTN12912185 https://doi.org/10.1186/ISRCTN12912185

Conventional Versus Automated Measurement of Blood Pressure in the Office

Submission date 11/05/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/06/2006	**Overall study status** Completed	
Last Edited 08/01/2021	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00325832

Secondary identifying numbers
392-2005

Study information

Scientific Title
Conventional Versus Automated Measurement of Blood Pressure in the Office

Acronym
The CAMBO Study

Study objectives
Automated office systolic blood pressure (SBP) recordings in routine clinical practice using the BpTRU device will reflect more accurately the mean awake ambulatory systolic blood pressure (BP) than manual BP readings taken with conventional mercury sphygmomanometry. This should lead to improvements in the management of systolic hypertension with optimization of drug therapy in practices using the BpTRU device.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Sunnybrook Research Ethics Board (REB) on 20/10/2005, reference number: 392-2005

Study design
A cluster randomized, controlled, clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Systolic hypertension

Interventions
Measurement of blood pressure using automated office BP with a target of 135 mmHg versus office mercury sphygmomanometer with a target of 140 mmHg

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
Differences in SBP between the mean awake ambulatory BP and the manual office BP versus the difference in SBP between the mean awake ambulatory BP and the automated office BP

Secondary outcome measures
1. Differences in SBP between the mean awake 24-hour ambulatory BP and the manual office BP versus the automated BP
2. Differences in SBP between the mean nocturnal ambulatory BP and the manual office BP versus the automated BP
3. Differences in coefficients of correlation (r value) between the awake ambulatory BP and the manual versus automated office BP
4. Differences in the coefficients of correlation between the manual office SBP versus the automated BP versus the mean awake, 24-hour or nocturnal ambulatory SBP
5. Differences in the primary outcome between men and women
6. Adverse effects related to management of hypertension with manual versus automated BP
7. Differences in intensity of drug therapy for manual versus automated office BP patients
8. Frequency of medication changes for manual versus automated office BP patients
9. Cost of drug therapy at year two for manual versus automated office BP patients
10. Clinical events of serious adverse events reported for manual versus automated office BP patients

Overall study start date
15/01/2006

Completion date
15/01/2008

Eligibility

Key inclusion criteria
Both treated and untreated patients with systolic hypertension under routine family physician (FP) care. For untreated patients, routine office SBP as measured by the patient's FP at the last routine office visit using a mercury device must have SBP ≥160 mmHg and diastolic blood pressure (DBP) ≤95 mmHg. For patients already receiving antihypertensive therapy, the last routine office BP as measured by the patient's FP using mercury sphygmomanometry must be SBP ≥140 mmHg and DBP ≤90 mmHg.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
500

Total final enrolment
461

Key exclusion criteria
1. Presence of target organ damage such as myocardial infarction (MI), stroke, and serum creatinine twice the upper limit of normal
2.Diabetes mellitus treated with insulin or oral hypoglycemic therapy
3. Secondary hypertension
4. Participation in another research study involving measurement of BP
5. Patient's insistence on using self BP measurement outside of the study
6. Any conditions or circumstances which might preclude the successful completion of the study

Date of first enrolment
15/01/2006

Date of final enrolment
15/01/2008

Locations

Countries of recruitment
Canada

Study participating centre
2075 Bayview Avenue
Toronto
Canada
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Sponsor information

Organisation
Heart and Stroke Foundation of Ontario (Canada)

Sponsor details
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Sponsor type
Charity

ROR
https://ror.org/00qbpyp73

Funder(s)

Funder type
Charity

Funder Name
Heart and Stroke Foundation of Ontario

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	01/08/2012	08/01/2021	Yes	No