

Conventional Versus Automated Measurement of Blood Pressure in the Office

Submission date 11/05/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 19/06/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 08/01/2021	Condition category Circulatory System	☐ 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)
NCT00325832

Protocol serial number
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

Primary study design

Interventional

Study design

A cluster randomized, controlled, clinical trial

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/00qbpyp73>

Funder(s)

Funder type

Charity

Funder Name

Heart and Stroke Foundation of Ontario

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?
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[Results article](#)

results

01/08/2012

08/01/2021

Yes

No