Comparison of blood pressure measurements using an automated blood pressure device in community pharmacies and physicians offices

Submission date	Recruitment status	Prospectively registered
25/07/2012	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
09/08/2012	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
04/08/2014	Circulatory System	

Plain English summary of protocol

Background and study aims

Accurate measurement of blood pressure is the foundation of appropriate diagnosis, treatment and on-going management of hypertension (high blood pressure). Automated blood pressure devices in community settings such as pharmacies provide opportunities for additional blood pressure measurement; however it is important to ensure these measurements are accurate and valid when compared to those taken in the physicians offices using the same devices. The aim of the study is to assess whether blood pressure readings assessed with an automated device differed according to the setting in which they were taken, specifically in community pharmacies compared to physicians offices.

Who can participate?

Community dwelling adults aged 65 years and older registered with five family physicians.

What does the study involve?

Five family physician offices mailed invitations to their patients aged 65 years and older to participate in the trial. Eligible and consenting adults are randomly allocated to one of two blood pressure measurement sequences:

- 1. Pharmacy, physicians office, pharmacy OR
- 2. Physicians office/pharmacy/physicians office

Automated blood pressure devices (BpTRU) are used in both settings.

What are the possible benefits and risks of participating?

Participants have their blood pressure assessed at three visits. If it is high, their family physician and pharmacist are notified. There are no side effects as only blood pressure is being monitored.

Where is the study run from?

The lead centre is the Bruyere Research Institute in Ottawa. The trial takes place in the two communities of Collingwood and Creemore, in Ontario, Canada.

When is the study starting and how long is it expected to run for? The trial began in November 2009 and finished in July 2012. Participants were recruited from April 2010 to June 2010.

Who is funding the study?
Canadian Stroke Network, a National Centre of Excellence and the Bruyere Research Institute

Who is the main contact? Prof Larry W Chambers lchambers@bruyere.org

Study website

http://chapprogram.ca

Contact information

Type(s)

Scientific

Contact name

Prof Larry Chambers

Contact details

Bruyère Continuing Care 43 Bruyere Street Ottawa Canada K1N5C8 lchambers@bruyere.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Comparison of blood pressure measurements using an automated bood pressure device in community pharmacies and physicians offices: the Collingwood-Creemore randomized controlled trial

Study objectives

Blood pressure measurements in a community pharmacy are comparable to blood pressure measurements in a physician office.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Bruyere Continuing Care Research Ethics Board, November 2009

Study design

Adults aged 65 and over randomly allocated to pharmacy/physicians office/pharmacy or physicians office/pharmacy/physicians office sequences.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Hypertension and related diseases

Interventions

Five family physician offices mailed invitations to their patients aged 65 years and older to participate in the trial. Eligible and consenting adults are randomly allocated to one of two blood pressure measurement sequences: pharmacy/physicians office/pharmacy or physicians office/pharmacy/physicians office. Automated blood pressure devices (BpTRU) are used in both settings.

Intervention Type

Device

Phase

Not Applicable

Primary outcome measure

After trial participants attended the first session to have their blood pressure measured, they were asked to come to the next two visits with less than a week between visits. The mean time interval to complete the three BP measurements for Arm A versus Arm B did not significantly differ (Arm A = 11.1 days versus Arm B = 11.8 days (p=0.36)).

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/04/2010

Completion date

30/09/2010

Eligibility

Key inclusion criteria

Community dwelling adults aged 65 years and older registered with five family physicians

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

300

Key exclusion criteria

Patients in hospital or living in long-term care facilities.

Date of first enrolment

01/04/2010

Date of final enrolment

30/09/2010

Locations

Countries of recruitment

Canada

Study participating centre Bruyère Continuing Care

Ottawa Canada

K1N5C8

Sponsor information

Organisation

Bruyere Research Institute (Canada)

Sponsor details

43 Bruyere Street Ontario Ottawa Canada K1N 5C8

Sponsor type

Research organisation

Website

http://www.bruyere.org

ROR

https://ror.org/05bznkw77

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Stroke Network (Canada)

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 09/04/2013 Yes No