Home Blood Pressure Monitoring and blood pressure (BP) control

Submission date Recruitment status Prospectively registered 14/08/2003 No longer recruiting [X] Protocol [] Statistical analysis plan Registration date Overall study status 08/09/2003 Completed [X] Results Individual participant data **Last Edited** Condition category 18/03/2010 Circulatory System

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number NCT00202137

Secondary identifying numbers

NA 4882

Study information

Scientific Title

Acronym

HBPM

Study objectives

Hypertension is a common problem in Canada with a prevalence of about 15%. The goal of hypertension therapy should be to maximize blood pressure control. Home Blood Pressure Monitoring (HBPM) devices are available and many patients are using them. The role that self-monitoring of blood pressure can play in optimizing blood pressure control is unclear. We hope to clarify the role of home blood pressure monitoring in the treatment of hypertension and explore how it may affect patient and physician behaviours related to blood pressure management. This study will compare a group of hypertensive patients who use HBPM with those who do not use these devices.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Hypertension

Interventions

Patients in the intervention group are provided with a home blood pressure monitor that they are to use at least once a week and report the BP measurements to their physician at each follow up visit.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. The mean daytime blood pressures on Ambulatory Blood Pressure Monitoring (ABPM)
- 2. The mean night-time blood pressures on ABPM
- 3. Achieving Blood Pressure (BP) target at end of study
- 4. Achieving 10% drop in the mean nighttime blood pressures

Secondary outcome measures

- 1. Patient lifestyle changes
- 2. The number of visits for hypertension
- 3. Compliance with hypertensive medication use
- 4. Compliance with the intervention
- 5. Intensity of treatment
- 6. Frequency of lifestyle counselling by physician
- 7. Quality of Life as measured by 36-item Short Form health survey (SF-36)

Overall study start date

01/07/2002

Completion date

01/11/2006

Eligibility

Key inclusion criteria

- 1. Adults (age 18 and older) who are patients of family physicians
- 2. Must be diagnosed with essential hypertension but not have yet achieved target levels

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

630

Key exclusion criteria

- 1. A diagnosis of secondary hypertension
- 2. Pregnancy

- 3. Hypertension management primarily by a consultant
- 4. A disability that precludes use of a home blood pressure monitor
- 5. Enrolled in another hypertension trial
- 6. White coat hypertension

Date of first enrolment

01/07/2002

Date of final enrolment

01/11/2006

Locations

Countries of recruitment

Canada

Study participating centre Centre for Studies in Primary Care

Kingston, Ontario Canada K7L 5E9

Sponsor information

Organisation

Heart and Stroke Foundation of Ontario (Canada)

Sponsor details

1920 Yonge Street 4th Floor Toronto, Ontario Canada M4S 3E2 +1 416 489 7100 mail@hsf.on.ca

Sponsor type

Charity

ROR

https://ror.org/00qbpyp73

Funder(s)

Funder type

Charity

Funder Name

Heart and Stroke Foundation of Ontario (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?
<u>Protocol article</u>	protocol	22/12/2003		Yes	No
Results article	results	28/06/2005		Yes	No