

Intensive Scheduled Management strategy for improving blood pressure control in patients in primary care

Submission date 14/08/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 08/09/2003	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 19/10/2007	Condition category Circulatory System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NA 4884

Study information

Scientific Title

Acronym

ISM

Study objectives

Comparing intensive scheduled management of hypertension (aggressive achievement of target blood pressure over 16 weeks) with usual management of hypertension.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Hypertension

Interventions

This study is designed to test the premise that guidelines, to be effective in primary care, need to be operationalised for the practitioner. To this end we have devised a protocol where medications are initiated at the recommended starting dose and increased by one recommended increment before adding the next drug. The goal is to increase the medications over the 16-week period such that, if necessary to reach the target blood pressure level, a patient is on a medium dose of three different antihypertensive agents.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Blood pressure control on 24-hour Ambulatory Blood Pressure Monitoring (ABPM), measured at 16 weeks and one year.

Key secondary outcome(s)

1. Patient quality of life
2. Physician compliance with the intensive protocol
3. Patient compliance with medication
4. Adverse effects

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. A diagnosis of secondary hypertension
2. Pregnancy
3. Hypertension management primarily by a consultant
4. Inability to provide informed consent

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

The Heart and Stroke Foundation of Ontario (Canada)

ROR

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

Funder(s)

Funder type

Charity

Funder Name

The Heart and Stroke Foundation of Ontario (Canada)

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?
Protocol article	Protocol	22/12/2003		Yes	No