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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 [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/09/2003	**Overall study status** Completed	
Last Edited 19/10/2007	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Marshall Godwin

Contact details
Centre for Studies in Primary Care
220 Bagot Street
Kingston, Ontario
Canada
K7L 5E9
+1 613-549-4480
godwinm@post.queensu.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

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

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

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
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

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)

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
The 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?
Protocol article	Protocol	22/12/2003		Yes	No