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Different blood pressure targets for people with a history of stroke or transient ischaemic attack (TIA) in Primary Care Clinical Sciences care

Submission date
12/02/2009

Registration date
18/02/2009

Last Edited
07/07/2016

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
RG_08_076

Study information

Scientific Title
A randomised controlled trial of different blood pressure targets for people with a history of stroke or transient ischaemic attack (TIA) in primary care

Acronym
Past BP

Study objectives
The principal question addressed by the study is whether having a more intensive blood pressure (BP) target in patients who have had a stroke or transient ischaemic attack (TIA) in primary care will lead to a lower BP and what will be the impact on patient quality of life?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Warwickshire Research Ethics Committee, 22/12/2008, ref: 08 H12111 21

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Stroke prevention

Interventions
Patients will be recruited from approximately 50 practices. Participants will be randomised to one of two treatment arms:
1. The intensive treatment arm will have a target systolic BP of 130 mmHg, or 10 mmHg reduction in systolic BP if baseline systolic BP is less than 140 mmHg
2. The standard treatment arm will have a target systolic BP of 140 mmHg as per current national guidelines

Each patient will remain in the study for one year. Patients will be reviewed at 1 - 3 month intervals by their surgery practice nurse dependent on their level of blood pressure and referred to their GP if their blood pressure is raised. Both nurses and GPs will follow algorithms based on the National Clinical Guidelines for Hypertension with regard to sequencing of agents and dose. Patients will be followed up at 6 and 12 months after their initial appointment by the research team.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Change in systolic blood pressure between baseline and twelve months.

Key secondary outcome(s))
1. Additional measures of blood pressure:
1.1. Diastolic blood pressure: change between baseline and six months
1.2. Change in systolic and diastolic blood pressure between baseline and 12 months
1.3. Change in mean daytime ambulatory systolic BP between baseline and twelve months
2. Measures of adherence:
2.1. GP adherence to protocol will be monitored by analysis of treatment decisions made at each GP follow up in the first twelve months
2.2. Patient adherence with prescribed medication will be assessed using:
2.2.1. Morisky's four item self report scale (questionnaire)
2.2.2. Patient attendance at planned reviews by practice nurse/GP
2.2.3. Electronic prescription data. This will be extracted from the practice computer systems, and will provide information regarding maximum compliance in terms of number of prescriptions requested (number of days for which medication has been prescribed divided by total number of days in each follow up period).
3. Side effects and tolerability:
3.1. Symptom questionnaire
3.2. Quality of life: 36-item short form health survey (SF-36) and EQ-5D questionnaires
4. Clinical end-points: major cardiovascular events (composite of fatal and non-fatal stroke, myocardial infarction or fatal coronary heart disease and other cardiovascular death) obtained through practice data
5. Other clinical outcome measures:
5.1. All cause mortality
5.2. Cognitive function (Mini Mental State Examination [MMSE] questionnaire)
5.3. Hospital admissions classified by discharge diagnosis
5.4. The individual components of the Primary Care Clinical Sciences care clinical outcome measure
6. Adverse events: additional adverse events (other than those covered by the outcome measures described above) will be recorded at six and twelve months
7. Resource use and costs: health sector and private sector use and costs will be recorded at six and twelve months on the case report form

Completion date
31/07/2012

Eligibility

Key inclusion criteria
Participants that are aged 18 years and over (either sex), on the practice TIA/stroke register with a validated diagnosis.

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Participants that:
1. Have systolic BP less than 125 mmHg at baseline
2. Are already taking three or more anti-hypertensive agents; orthostatic hypotension (greater than 20 mmHg postural change in systolic BP)
3. Have diabetes mellitus with microalbuminuria or other condition for which a patient has a lower treatment target specified

Date of first enrolment
01/07/2008

Date of final enrolment
31/07/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (ref: RP-PG-0606-1153)

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?
Results article	results	24/02/2016		Yes	No
Protocol article	protocol	09/08/2010		Yes	No