

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 18/02/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/07/2016	Condition category Circulatory System	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

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

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 measure

Change in systolic blood pressure between baseline and twelve months.

Secondary outcome measures

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

Overall study start date

01/07/2008

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

610

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

England

United Kingdom

Study participating centre
University of Birmingham
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Sponsor information

Organisation
University of Birmingham (UK)

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Sponsor type
University/education

Website
<http://www.bham.ac.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

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