

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

<b>Submission date</b> 12/02/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 18/02/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/07/2016	<b>Condition category</b> 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

**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?
<a href="#">Results article</a>	results	24/02/2016		Yes	No
<a href="#">Protocol article</a>	protocol	09/08/2010		Yes	No