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Blood Pressure Variability (BPV) and stroke: its measurement, natural history and prognosis

Submission date
01/05/2013

Recruitment status
No longer recruiting

Registration date
30/05/2013

Overall study status
Completed

Last Edited
21/02/2019

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
High blood pressure is a major risk factor for stroke. Recently, variation in blood pressure or blood pressure variability (BPV) has also been reported to be associated with stroke. Commonly used blood pressure lowering drugs have different effects on BPV which may, in part, explain the overall effect on the risk of stroke. However, more research is required to understand fully the natural history of BPV following stroke and how it can be used as an indication of stroke in the future. This study will test if BPV is an indication of risk of stroke and the possibility of future research.

Who can participate?
Patients with minor stroke, who are managed in an outpatient setting and stroke patients managed in an inpatient setting, will be recruited within 24 hours of onset of symptom.

What does the study involve?
For all patients, BPV will be measured at several time intervals using different BP recorders. Patients will be followed-up over a 12-month period. BPV measurements will be repeated at hospital discharge (for admitted patients) and at 1, 3 and 12 months (in all patients). Patients will be asked to complete a questionnaire about the tolerability of BP measurement devices.

What are the possible benefits and risks of participating?
There will not be any guaranteed direct benefits from participating in this study. The results of this study may help design future studies. The possible risks will be:
1. Exposure to small amount of radiation if a CT scan is performed. No harmful effects have been reported due to this exposure.
2. The blood pressure cuff applies only a gentle pressure to the fingers to enable a blood pressure recording. This may cause a slight tingling sensation in the fingers, but this should not be painful or cause any harm.

Where is the study run from?
The study is run from University Hospitals of Leicester, Norfolk and Norwich University Hospitals and John Radcliffe Hospital, Oxford.

When is the study starting and how long is it expected to run for?
The study begins in July 2013 and is expected to run till June 2016.

Who is funding the study?
The Stroke Association (UK) and British Heart Foundation (UK)

Who is the main contact?
Prof. Thompson Robinson
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Contact information

Type(s)
Scientific

Contact name
Prof Thompson Robinson

Contact details
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Additional identifiers

Protocol serial number
V1.0

Study information

Scientific Title
Blood Pressure Variability - definition, natural history and prognosis following acute stroke

Acronym
BPV-Stroke

Study objectives
What is the most appropriate technique to measure and define blood pressure variability in an acute stroke and Transient Ischaemic Attack (TIA) population, including beat-to-beat blood pressure monitoring, the timing and frequency of casual blood pressure measurements and the role of 24-hour and home blood pressure monitoring?

Ethics approval required
Old ethics approval format

Ethics approval(s)

NRES Committee London - South East, Bristol Research Ethics Committee Centre, Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, Tel: +44 (0)117 342 1331, Email: nrescommittee.London-southeast@nhs.net, 25/07/2013, REC ref: 13/LO/0979

Study design
Cohort observational study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Acute ischaemic stroke and transient ischaemic attack

Interventions
Baseline demographic and clinical data will be recorded by the research nurses, including variables known to be associated with outcome: age, premorbid and baseline mRS score, stroke syndrome (Oxfordshire Community Stroke Project classification), co-morbidities particularly ischaemic heart disease, previous stroke, diabetes, atrial fibrillation), NIHSS score, neuroimaging results, and thrombolysis treatment.
1. Casual BP: In all recruited patients, baseline casual BP will be calculated as a mean of two sets of three supine brachial BP readings taken 10 minutes apart in the hemiparetic arm, using a UA767 BP monitor (enhanced casual BP). In addition, the results of routine clinical bedside four-times-daily BP measurements will also be recorded (routine casual BP), as will a record of administered BP-lowering therapy
2. 24-hour BP: 24-hour BP monitoring will be performed immediately after casual BP measurement using a Spacelabs-90207 recorder, programmed to record BP at 20-minute intervals during the day (0700 to 2200) and 60-minute intervals during the night (2200 to 0700). BP recorded with the 24-hour BP monitor will be calibrated against casual BP at the beginning of the recording. Any patient in whom there is a discrepancy between the two methods >5mmHg in SBP and diastolic BP will be excluded
3. Beat-to-beat BP: In addition, all patients will undergo at least two consecutive periods of 10-minute beat-to-beat non-invasive BP monitoring in the supine position using the middle finger of the non-hemiparetic hand with a Finometer device. The servo adjust mechanism of the Finometer will be switched off during the recording period, but applied at 10-minute intervals during the monitoring period. In addition to mean beat-to-beat BP levels and BPV, this will also allow the estimation of BRS.
4. Pulse wave analysis: Before and after the beat-to-beat BP recording, pulse wave analysis will be carried out simultaneously at the brachial and femoral sites, repeated at the carotid and femoral sites, using the Vicorder device. This is carried out by the use of a standard BP cuff, with the pressure elevated as high as the diastolic BP level to obtain a non-invasive arterial pressure wave. Coupled with cardiac monitoring and a standardised measurement from the sternal notch to the two sites of analysis (femoral and brachial), Pulse Wave Velocity (PWV) can be calculated. The Vicorder device comes integrated with a mathematical function that can estimate central aortic indices, including central BP and Augmentation Index (AI), from peripheral waveform analysis when calibrated to brachial BP. The mean of three readings at each time-point will be used to estimate PWV (carotid-femoral, carotid-brachial), AI and central BP.
5. Patients will be invited to complete a questionnaire exploring the tolerability of the BP measurement devices, in particular the Finometer, Vicorder and 24-hour BP recorder

6. All patients will be asked to provide consent to their medical record being flagged, so that information on hospital re-admission (for stroke and other cardiovascular diseases) and mortality can be obtained over the follow-up period

Casual, beat-to-beat and 24-hour BP measurements will be repeated at hospital discharge (for admitted patients), and at 1, 3 and 12 months following stroke onset (for all patients). At hospital discharge, patients will also be provided with a British Hypertension Society approved Home BP monitor (with built-in memory) and appropriately sized cuff. Patients will be asked to measure their BP on two occasions in the morning and evening before any usual medication (i.e. four readings per day) for a period of 7 days before and after the 1, 3 and 12 month assessments. Patients will be trained in the use of the Home BP monitor prior to hospital discharge by a Research Nurse

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Death and Dependency (Modified Rankin Score >2) at 3 months post-stroke

Key secondary outcome(s))
The prognostic significance of individual BPV measures from routine and enhanced casual, beat-to-beat, central, 24-hour and Home BP measurements will be assessed at the following time-points. In addition, the mRS score will be repeated and a record made of BP-lowering, statin and other treatment with vasoactive effects.

1. Short-term (72 hours)
1.1. Neurological deterioration/ improvement (NIHSS score increase/ decrease by >4 points, respectively)
2. Hospital discharge
2.1. Mortality
2.2. Recurrent TIA/stroke
2.3. Major cardiovascular events (non-fatal and fatal stroke, myocardial infarction and systemic embolism) mRS
2.4. Length of hospital stay
3. Medium-term (1 and 3 months)
3.1. Mortality
3.2. Recurrent TIA/stroke
3.3. Major cardiovascular events mRS
3.4. Cognitive dysfunction assessed using the Montreal Cognitive Assessment tool (MoCA); a brief cognitive screening tool with high sensitivity and specificity for detecting mild cognitive impairment in patients performing within the normal range of the mini-mental state examination
4. Long-term (1 year)
4.1. Mortality
4.2. Recurrent TIA/stroke
4.3. Major cardiovascular events mRS
4.4. Cognitive dysfunction assessed
4.5. Time to death/hospital re-admission

Completion date
30/06/2016

Eligibility

Key inclusion criteria
Acute TIA/ minor stroke (managed in an outpatient setting or with an NIHSS score <6) and stroke (managed in an inpatient setting) patients will be recruited within 24 hours of symptom onset.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Inability to provide informed consent
2. Significant pre-stroke dependency (mRS >3)
3. Co-existing life-threatening with a life expectancy <3 months
4. Placed on an end-of-life care pathway
5. Atrial fibrillation
6. Pre-existing BB use (and need for continuation in the view of the treating clinician)

Date of first enrolment
01/07/2013

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Robert Kilpatrick Clinical Sciences Building
Leicester
United Kingdom
LE2 7LX

Sponsor information

Organisation
University of Leicester (UK)

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Charity

Funder Name
Stroke Association

Alternative Name(s)
TheStrokeAssociation, TheStrokeAssoc

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
British Heart Foundation

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request. Details of whom the data can be requested are yet to be confirmed, but will be provided nearer to publication.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		21/02/2019	21/02/2019	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes