

The effect of antihypertensive treatment with Lisinopril and Labetalol on baroreflex sensitivity in stroke

Submission date 19/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 19/12/2005	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 07/04/2014	Condition category Circulatory System	☐ Individual participant data
		☐ Record updated in last year

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

N0203157787

Study information

Scientific Title

Study objectives

What is the effect of treatment with the antihypertensive agents lisinopril and labetalol on baroreflex sensitivity (BRS) in patients with previous stroke or transient ischaemic attack (TIA)?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Cardiovascular: Stroke

Interventions

Our hypothesis is that treatment with the antihypertensive agents lisinopril and labetalol produces an improvement in baroreflex sensitivity in stroke patients.

All patients seen on the rapid access stroke clinic or discharged home from the acute stroke unit with a diagnosis of stroke in whom the physician responsible for their care considers antihypertensive agents are indicated will be considered for this study. If they fulfill the inclusion criteria, have none of the exclusion criteria and give consent then they are entered into the trial.

Participants will receive lisinopril and labetalol consecutively in a randomly allocated order with a 2 week washout period between each treatment. The dose of each drug will be carefully titrated up until the desired response in blood pressure is seen (a fall in systolic blood pressure of 10mmHg). Periods of monitoring will be conducted immediately prior to each treatment and after they have been on their target dose for 14 days.

A flow chart summarising what will happen to each participant is included at the end of the study protocol.

The period of monitoring will involve initially 2 periods of casual blood pressure (BP) monitoring (3 readings repeated 10 minutes apart). Participants will then undergo recording of beat-to-beat blood pressure monitoring, using the Portapres non-invasive BP recording device. This involves the application of an inflatable cuff to the finger, which can cause some tingling, but should not cause any discomfort. At the same time, an ECG monitor is attached, and respiratory frequency is measured by means of an abdominal wasteband. 3 sequential readings are taken using this equipment, and analysis of this data using spectral and sequence analysis methods provides an estimate of BRS. Participants will also have recordings of central arterial stiffness performed using applanation tonometry to obtain information on arterial waveforms and pulse wave velocity. This is a non-invasive technique which involves the application of a probe over the radial

artery at the wrist, the carotid artery in the neck, and the femoral artery in the groin (although there will be no need to remove undergarments). This period of monitoring should take approximately one hour.

Each participant will also have the following data collected: The severity of their stroke (using the NIH stroke scale), stroke classification, side of the lesion, neuroimaging findings, presence of carotid artery disease, vascular risk factors and past vascular events.

Throughout the study, participants will be monitored for side effects related to their trial medication such as symptomatic bradycardia or hypotension. Blood tests will also be taken prior to commencing treatment and after 1 week to check for any deterioration in renal function. If any side effects occur, the treatment will be withdrawn.

In view of the scientific nature of the studies, their designs have been guided by perceived gaps in current medical literature, rather than direct user involvement. However, a detailed patient information leaflet, and an opportunity to ask questions, will be provided.

The methods used for obtaining BRS and arterial compliance information have been used extensively in other trials, in both stroke patients, and other clinical conditions.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

lisinopril, labetalol

Primary outcome(s)

Change in BRS seen as a result of treatment with lisinopril and labetalol.

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/08/2006

Eligibility

Key inclusion criteria

Patients with previous stroke or transient ischaemic attack (TIA).

1. Age > 18 years
2. Clinical diagnosis of stroke > 8 weeks ago
3. Stable neurology
4. Clinical indication for antihypertensive treatment
5. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Lower age limit

18 Years

Sex

Not Specified

Key exclusion criteria

1. Excessive ectopic activity
2. Atrial fibrillation
3. Contraindication to beta blocker therapy
4. Contraindication to ace inhibitor therapy
5. Clinical indication for treatment with ace inhibitor, beta blocker or angiotensin II antagonist other than hypertension
6. Conditions independently associated with autoimmune dysfunction (acute myocardial infarction, unstable angina, active heart failure, diabetes mellitus)

Date of first enrolment

07/01/2005

Date of final enrolment

31/08/2006

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Royal Devon & Exeter Hospital (Wonford)

Exeter

United Kingdom

EX2 5DW

Sponsor information**Organisation**

Funder(s)

Funder type

Government

Funder Name

Royal Devon & Exeter NHS Foundation Trust (NHS R&D Support Funding)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration