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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/12/2005	**Overall study status** Completed	
Last Edited 07/04/2014	**Condition category** Circulatory System	

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
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
07/01/2005

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

Age group
Not Specified

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
23 participants, no control group

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 angiotesin 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
England

United Kingdom

Study participating centre
Royal Devon & Exeter Hospital (Wonford)
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2005 Update - Department of Health

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Funder type
Government

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

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