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The effect of dietary nitrate supplementation on dynamic cerebral autoregulation in ischaemic stroke

Submission date 16/04/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 06/06/2014	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/12/2017	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to find out if taking in nitrate through the diet has any effect on the brains ability to regulate blood flow in stroke patients. The ability to maintain a constant blood flow within the brain despite changes in the body's blood pressure is termed cerebral autoregulation. A high nitrate diet has previously been shown to improve blood flow to parts of the brain. Cerebral autoregulation is impaired in stroke and nitrate may have a role. It would be useful to know if beetroot juice has any effect on cerebral autoregulation as it could lead to further research in its use as a treatment in stroke patients. We can detect changes in the blood flow within the brain by placing ultrasound probes over the temples of the head. This is called transcranial ultrasound and is non-invasive. Any changes in the ultrasound signals from the blood flow in the brain are recorded and analysed via the computer.

Who can participate?
Participants will be invited to participate if they have had a stroke in the past 14 days, are able to attend hospital twice and are able to swallow liquids. Participants need to be between the ages of 18 and 90.

What does the study involve?
Participants will be randomly assigned to drink a small amount of either beetroot juice or a placebo (dummy) juice and the response to this will be assessed 2 hours after drinking the juice by taking an ultrasound of the head just by the temples. By taking a blood sample we will be able to tell the amount of nitrates in the system.

What are the possible benefits and risks of participating?
There is expected to be no immediate benefit to study participants but the results collected will help inform future larger studies and potential for use in clinical practice. There are no major risks or side effects associated with treatment or the study.

Where is the study run from?
Torbay Hospital (UK)

When is the study starting and how long is it expected to run for?
The study started in May 2014 and is expected to run until November 2014.

Who is funding the study?
South Devon Healthcare NHS Foundation Trust (UK).

Who is the main contact?
Dr Isam Salih
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of dietary nitrate supplementation on dynamic cerebral autoregulation in ischaemic stroke: a pilot randomised controlled trial

Study objectives
We hypothesize that subjects within 2 weeks of stroke onset who receive a single dose of dietary nitrate will show a significantly lower Correlation Coefficient (nMx) (i.e., more favorable dynamic cerebral autoregulation) than subjects who receive placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration submission pending

Study design
Single-centre feasibility/pilot study, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please email sdhct.research@nhs.net or phone +44 (0) 1803 656635 to request a patient information sheet

Health condition(s) or problem(s) studied
Stroke

Interventions
1. Transcranial acoustic window with transcranial ultrasound
2. Measuring dynamic cerebral autoregulation
3. Venous blood sample for plasma nitrate
4. Clinical neurological examination
5. Thigh blood pressure cuff inflation and deflation
6. Participants are randomized to drink 70 ml of either beetroot juice or placebo juice

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The Correlation Coefficient (nMx), a marker of dynamic cerebral autoregulation, at 2 hours following ingestion of the investigational product

Secondary outcome measures
1. Plasma nitrate level
2. Mean arterial blood pressure
3. Standard cerebral haemodynamics

4. National Institutes of Health Stroke Scale (NIHSS)
5. Modified Rankin Score (mRS)

Measured at 2 hours following ingestion of the investigational product.

Overall study start date
01/05/2014

Completion date
04/11/2014

Eligibility

Key inclusion criteria
1. Subjects must have a confirmed onset of acute ischaemic stroke within the last 14 days
2. Age 18-90
3. Able to lie supine and still for 30 minutes
4. Able to take liquid orally
5. Able to give full informed consent
6. Adequate temporal acoustic window as assessed with transcranial doppler ultrasound

Participant type(s)
Patient

Age group
Other

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
16

Key exclusion criteria
1. Stroke onset within 24 hours
2. Haemorrhagic stroke
3. Pregnant women
4. Dysphagia precluding oral intake of liquid
5. Inadequate temporal acoustic window for transcranial ultrasound
6. Exclude vasoactive drugs including calcium channel blockers
7. Regularly taking organic nitrates, nicorandil, glitazones, phosphodiesterase inhibitors
8. Pre-existing dementia
9. Significant carotid stenosis >70% on carotid doppler
10. Severe peripheral vascular disease

Date of first enrolment
01/05/2014

Date of final enrolment
04/11/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Stroke Department
Torquay
United Kingdom
TQ2 7AA

Sponsor information

Organisation
South Devon Healthcare NHS Foundation Trust (UK)

Sponsor details
Research and Development Dept.
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Sponsor type
Hospital/treatment centre

Website
http://www.sdhct.nhs.uk/

ROR
https://ror.org/05374b979

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
South Devon Healthcare NHS Foundation Trust (UK)

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