

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

<b>Submission date</b> 16/04/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/06/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/12/2017	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 brain's 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**  
Dr Isam Salih

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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](mailto: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.

South Devon Healthcare NHS Foundation Trust

Horizon Centre

Torbay Hospital

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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