

# Simvastatin in aneurysmal subarachnoid haemorrhage: a multicentre, randomised controlled, clinical phase III study

<b>Submission date</b> 15/02/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/04/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/08/2014	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Background and study aims.

A blood vessel abnormality called an aneurysm can cause a bleed within the head. We wish to study the potential benefits of giving a standard cholesterol lowering drug (called Simvastatin) after a bleed has occurred. This is a licensed medication used regularly in the treatment for other vascular conditions including heart attacks and strokes, but it is not licensed at this stage for the treatment of a bleed in the brain. In some instances we may also wish to find out whether the patients genetic makeup can influence the course of your disease, its clinical outcome, or response to the medicine that we are testing.

Who can participate?

Patients aged 18-65 years in whom the admitting neurosurgeon has diagnosed a bleed onto the surface of the brain, called a subarachnoid haemorrhage (SAH). We propose to recruit approximately 800 people to the trial.

What does the study involve?

Patients will be allocated randomly (like a flip of the coin) to taking either Simvastatin 40mg or an inactive dummy drug called a placebo. The treatment will be administered as one tablet daily for up to 21 days. If the patient is discharged from the Neurosurgical Unit before 21 days, treatment will be stopped. Nobody (not even the doctors) will know which treatment is being given until the study is over. However, if necessary, the doctor will be able to find out which treatment has been given if any concern arises. Before they leave the hospital we will assess the patients level of recovery. Two short questionnaires will be sent to their home 6 months later asking about their current level of recovery and state of health.

What are the possible benefits and risks of participating?

In the event of taking Simvastatin we hope that this drug might help in recovery. However, this cannot be guaranteed. More likely, the information we obtain from this study may help us to improve on the treatment for future patients suffering from SAH.

Possible rare side effects of Simvastatin include muscle weakness or tenderness, headache, nausea or rash. However no regular side effects have been observed even in patients receiving

this treatment for many years. However, in the event of any serious unforeseen reactions, or if any concerns arise, the drug will be stopped immediately.

Where is the study run from?

Department of Neurosurgery, Cambridge University Hospitals NHS Foundation Trust

When is the study starting and how long is it expected to run for?

The study started in May 2006 and is expected to end in January 2014.

Who is funding the study?

British Heart Foundation

Who is the main contact?

Mr Peter J Kirkpatrick

pjk21@medschl.cam.ac.uk

**Study website**

<http://www.stashtrial.com>

## Contact information

**Type(s)**

Scientific

**Contact name**

Mr Peter Kirkpatrick

**Contact details**

Box 167

Addenbrooke's Hospital

Hills Road

Cambridge

United Kingdom

CB2 2QQ

## Additional identifiers

**EudraCT/CTIS number**

2006-000277-30

**IRAS number**

**ClinicalTrials.gov number**

NCT00731627

**Secondary identifying numbers**

STASH01

## Study information

## **Scientific Title**

### **Acronym**

STASH

### **Study objectives**

Can acute statin therapy reduce the incidence and duration of delayed ischaemic deficits following a subarachnoid haemorrhage (SAH)?

On 04/12/2012 the anticipated end date was changed from 01/05/2009 to 31/01/2014.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Thames Valley Research Ethics Committee, 06/07/2006, ref: 06/MRE12/26

### **Study design**

Multi-centre double-blind randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

<http://www.stashtrial.com/downloads.html>

### **Health condition(s) or problem(s) studied**

Subarachnoid haemorrhage

### **Interventions**

Simvastatin versus placebo

### **Intervention Type**

Drug

### **Phase**

Phase III

### **Drug/device/biological/vaccine name(s)**

Simvastatin

**Primary outcome measure**

Clinical outcome at six months

**Secondary outcome measures**

1. Short form questionnaire (SF-36) scores at six months
2. Incidence and duration of delayed ischaemic deficits
3. Need and intensity of delayed ischaemic deficits rescue therapy
4. Incidence of extracranial organ dysfunction and failure
5. Incidence and duration of extracranial organ support
6. Incidence and severity of sepsis
7. Length of intensive care and total acute hospital stay
8. Percentage of patients being discharged directly home
9. Reduction in intensive care requirements for those with sepsis

**Overall study start date**

01/05/2006

**Completion date**

31/01/2014

**Eligibility****Key inclusion criteria**

1. Patients aged 18-65 years
2. If the admitting neurosurgeon has a high index of suspicion of a spontaneous aneurysmal subarachnoid haemorrhage (good clinical history with convincing computerised tomography [CT] findings)
3. Any clinical grade accepted provided there is a reasonable prospect of survival
4. Delay to randomisation and initiation of trial medication, from the time of the presenting bleed, does not exceed 96 hours
5. Independent prior to the SAH

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

800

**Key exclusion criteria**

1. Unsalvageable patients: fixed and dilated pupils after resuscitation, and/or a devastating scan, which precludes definitive therapy
2. Already taking statin therapy
3. Those taking warfarin-type drugs
4. Pregnancy
5. Known renal or hepatic impairment
6. Suspected or known additional disease process, which threatens life expectancy (e.g. malignancy)
7. Known or strong suspicion of drug abuse, alcoholism, or those who are unlikely to be amenable to six-month follow up

**Date of first enrolment**

01/05/2006

**Date of final enrolment**

31/01/2014

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Box 167**

Cambridge

United Kingdom

CB2 2QQ

**Sponsor information****Organisation**

Cambridge University Hospitals NHS Foundation Trust (UK)

**Sponsor details**

Box 146

Addenbrooke's Hospital

Hills Road

Cambridge

England

United Kingdom

CB2 2QQ

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/04v54gj93>

## Funder(s)

**Funder type**

Charity

**Funder Name**

British Heart Foundaton (BHF) (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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2014		Yes	No