

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

Submission date 15/02/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/04/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/08/2014	Condition category 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?
Results article	results	01/07/2014		Yes	No