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

Submission date
15/02/2006

Recruitment status
No longer recruiting

Registration date
04/04/2006

Overall study status
Completed

Last Edited
12/08/2014

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 65years 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
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Contact information

Type(s)
Scientific

Contact name
Mr Peter Kirkpatrick

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00731627

Clinical Trials Information System (CTIS)
2006-000277-30

Protocol serial number
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

Primary study design
Interventional

Study design
Multi-centre double-blind randomised controlled trial

Study type(s)
Treatment

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(s)
Clinical outcome at six months

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

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
United Kingdom

England

Study participating centre
Box 167
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundaton (BHF) (UK)

Results and Publications

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				

Results article		01/07/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes