

Secondary Prevention of Acute Coronary Events. Reduction Of Cholesterol to Key European Targets: an open-label comparative investigation of efficacy, tolerance and health in 2,072 patients randomised to rosuvastatin or 'standard' simvastatin therapy following hospital admission for new definition myocardial infarction

Submission date 25/02/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/06/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/08/2011	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Alistair Hall

Contact details
The BHF Heart Research Centre G Floor
Jubilee Building
Leeds General Infirmary
Leeds
United Kingdom
LS1 3EX

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym

SPACE ROCKET

Study objectives

The aim of the SPACE ROCKET trial is to compare the clinical effectiveness of rosuvastatin 10 mg with simvastatin 40 mg on the surrogate endpoints of cholesterol lowering and tolerance, together with their ability to achieve key European cholesterol targets, in patients admitted to hospital for new definition myocardial infarction. The trial has been designed as an open-label, multi-centre, randomised, controlled, parallel group trial with equal randomisation of 2,072 patients. Consenting patients admitted to hospital for new definition myocardial infarction will be allocated to receive either rosuvastatin 10 mg or 'standard' treatment with simvastatin 40 mg for three months.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

New definition myocardial infarction

Interventions

Patients will be randomised to receive either:

1. Simvastatin 40 mg, OR
2. Rosuvastatin 10 mg

Please note that the anticipated end date of this trial was extended to the 31st March 2007 following an extension to the funding.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Rosuvastatin, simvastatin

Primary outcome measure

Achievement of European lipid targets (Low-Density Lipoprotein [LDL] cholesterol less than 2.5 mmol/l or Total Cholesterol [TC] less than 4.5 mmol/l) at three months.

Secondary outcome measures

1. Patient tolerance:
 - 1.1. Withdrawal from therapy at three months
 - 1.2. Self-reported side-effects at three months
2. Efficacy:
 - 2.1. Comparison of lipid parameters: TC, LDL cholesterol, High-Density Lipoprotein (HDL) cholesterol and triglycerides at three months
 - 2.2. Achievement of National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP) III (LDL cholesterol less than 100 mg/dl or 2.6 mmol/l) at three months
 - 2.3. Achievement of National Service Framework (NSF) targets (LDL cholesterol less than 3.0 mmol/l or TC less than 5.0 mmol/l) at three months
 - 2.4. Achievement of new UK Joint Society targets (LDL cholesterol less than 2.0 mmol/l or TC less than 4.0 mmol/l) at three months
3. Safety:
 - 3.1. Serious Adverse Events (up to and including three-month follow-up)
 - 3.2. Biochemical markers: Creatine Kinase (CK), Alanine aminotransferase (ALT), creatinine and proteinuria
4. Tertiary endpoints:
 - 4.1. Cardiovascular events
 - 4.2. Total mortality as monitored at three months
 - 4.3. Total mortality as monitored indefinitely via Office of National Statistics (extending beyond three-month trial follow-up)

Overall study start date

01/04/2005

Completion date

Eligibility

Key inclusion criteria

Patients with the following characteristics are eligible for this trial:

1. Within two weeks of new definition Myocardial Infarction (MI) defined as a typical rise of biochemical markers of myocardial necrosis with one or more of the following:
 - 1.1. ischaemic symptoms
 - 1.2. development of pathological Q waves on the Electrocardiogram (ECG)
 - 1.3. ECG changes indicative of ischaemia (ST segment elevation or depression)
 - 1.4. coronary artery intervention (e.g. primary coronary angioplasty)
2. Requiring secondary prevention with a statin in the opinion of the attending clinician
3. Patient must have given written informed consent prior to any trial-specific procedures

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

2072

Key exclusion criteria

Patients with the following characteristics are ineligible for this trial, at the discretion of the attending medical team:

1. Not suitable for statin therapy as determined by the attending clinician
2. Previous statin intolerance
3. Known contra-indication for statin use:
 - 3.1. hypersensitivity to the product
 - 3.2. active liver disease including unexplained, persistent elevations of serum transaminases and any serum transaminase elevation exceeding three times the Upper Limit of Normal (ULN)
 - 3.3. severe renal impairment
 - 3.4. myopathy
 - 3.5. concomitant cyclosporin
 - 3.6. existing polymyositis or dermatomyositis
 - 3.7. pre-disposing factors for myopathy/rhabdomyolysis, which include: moderate renal impairment, hypothyroidism, personal or family history of hereditary muscular disorders, alcohol abuse, situations where an increase in plasma levels may occur, concomitant use of fibrates
4. Already receiving simvastatin 80 mg or atorvastatin 80 mg at time of admission
5. Randomised to the trial during previous admission
6. Aged under 18 years at the time of recruitment
7. Women of childbearing potential not using an effective method of contraception
8. Women who are pregnant or breast-feeding
9. Participation in another pharmacotherapeutic study within the prior 30 days or currently receiving an experimental pharmacological agent
10. Taking drugs associated with rhabdomyolysis in combination with statins (i.e. strong

cytochrome P450-3A4 inhibitors such as erythromycin) or other concomitant drugs with special warnings or precautions (as per Summary of Product Characteristics [SPC] for both drugs), for example: fibrates, gemfibrozil, cyclosporin, nicotinic acid, azole antifungals, protease inhibitors, macrolide antibiotics, amiodarone, verapamil, diltiazem or nefazodone

11. Proteinuria ++/+++

12. Excess alcohol consumption (greater than 50 units per week)

Date of first enrolment

01/04/2005

Date of final enrolment

30/04/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

The BHF Heart Research Centre G Floor

Leeds

United Kingdom

LS1 3EX

Sponsor information

Organisation

University of Leeds (UK)

Sponsor details

Research Office

Room 7.11

Level 7

Worsley Building

University of Leeds

Leeds

England

United Kingdom

LS2 9NL

Sponsor type

University/education

ROR

Funder(s)

Funder type

Industry

Funder Name

AstraZeneca (UK)

Alternative Name(s)

AstraZeneca PLC, Pearl Therapeutics

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

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	01/12/2009		Yes	No
Results article	results of GEOSTAT-1 sub-study	01/06/2010		Yes	No