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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/06/2005	**Overall study status** Completed	
Last Edited 08/08/2011	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Prevention

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(s)
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.

Key secondary outcome(s))
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 Linase (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)

Completion date
30/04/2006

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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

United Kingdom

England

Study participating centre
The BHF Heart Research Centre G Floor
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
University of Leeds (UK)

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Industry

Funder Name
AstraZeneca (UK)

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics, AZ

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

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