ISRCTN05886349 https://doi.org/10.1186/ISRCTN05886349

The STARS (steroids against re-stenosis) trial: the use of peri-procedural oral corticosteriods to prevent in-segment re-stenosis after percutaneous coronary intervention

Submission date
03/10/2006

Recruitment status
No longer recruiting

Registration date
02/08/2007

Overall study status
Completed

Last Edited
19/05/2016

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CTA number: 22011/0001/001-0001

Study information

Scientific Title
The STARS (STeroids Against Re-Stenosis) trial: the use of peri-procedural oral corticosteriods to prevent in-segment re-stenosis after percutaneous coronary intervention

Acronym
The STARS (STeroids Against Re-Stenosis) trial

Study objectives
1. The peri-procedural use of oral corticosteroids in elective/acute patients undergoing percutaneous coronary intervention reduces the incidence of in-segment re-stenosis
2. The use of a chromium cobalt stent results in lower restenosis rates than bare metal stents in elective/acute patients undergoing percutaneous coronary intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Multicentre Research Ethics Committee (MREC), 05/05/2005, ref: 04/MREC2/061

Study design
Double blind 2 x 2 randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Atherosclerosis

Interventions

1. Prednisolone versus placebo
2. Chromium cobalt stent versus stainless steel stents

Steroid randomisation procedure:
Acute cases: patients will be randomised via block randomisation 24 hours before their procedure and assigned to the respective study arms by a closed envelope system
Elective cases: patients will be randomised via block randomisation at the time of their pre-admission clinic attendance (one-week prior to the procedure) and assigned to the respective study arms by a closed envelope system

Stent randomisation procedure:
Acute and elective cases: patients will be randomised via block randomisation at the time of their percutaneous coronary intervention procedure if no exclusion criteria are met and assigned to the respective study arms by a closed envelope system.

Steroid protocol:
Patients will be randomised to oral prednisolone or placebo. Patients will receive prednisolone 40 mg to start 24 hours pre-procedure and to continue for a total of 28-days.

Due to dual oral antiplatelet therapy plus oral corticosteroid use, all patients will receive empirical proton pump inhibitor cover (lansoprazole 15 mg/day for 28 days) for the duration of the corticosteroid course (advice taken from a consultant gastroenterologist).

Protocol for steroid withdrawal/step-down:
Due to the potential risk of adrenal suppression all patients will receive a step-down approach for steroid withdrawal. For the first 14 days patients will receive 40 mg prednisolone. The dose will then be tailed off over the next 14 days as shown below:

Day 1 to 14 = 40 mg
Day 15 to 19 = 20 mg
Day 20 to 24 = 10 mg
Day 25 to 28 = 5 mg

Registry:
Patients' full eligibility for study participation will not be known until the time of coronary angiography as a major inclusion criteria is a lesion of a reference diameter vessel greater than or equal to 3 mm. Lesions less than 3 mm are an exclusion criteria as National Institute for Clinical Excellence (NICE) guidelines advise the use of drug eluting stents in this setting. Therefore some patients will receive study medication up to this point. A registry will be kept of these patients and they will be followed up clinically (via telephone) but not angiographically.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Corticosteroids

Primary outcome measure

Angiographically documented in-segment re-stenosis.

Secondary outcome measures
1. Late loss
2. Target lesion revascularisation: defined as repeat intervention of re-stenotic lesions, which include the target site of the stent implantation or 5 mm proximal and distal in the same epicardial coronary artery
3. Target vessel revascularisation: defined as repeat intervention within the same epicardial coronary artery
4. Target vessel failure: target vessel revascularisation plus any peri-procedural complication related to the procedure
5. Myocardial Infarction (MI) related to the target vessel
6. Incidence of death
7. Unstable angina, congestive cardiac failure
8. Non-fatal MI
9. Q wave MI
9. Non-Q wave MI
10. Cardio-Vascular Accident (CVA)
11. Intracranial haemorrhage
12. Infarction
13. Repeat hospitalisation
14. Major/minor bleeding complications
15. Poor glycaemic control

Overall study start date
01/01/2006

Completion date
01/01/2009

Eligibility

Key inclusion criteria
1. Any patient awaiting percutaneous coronary intervention for symptomatic coronary artery disease (elective or acute)
2. Documented myocardial ischaemia
3. Coronary angiography demonstrating at least a 50% reduction of the luminal diameter in at least one native coronary artery (as measured by quantitative computerised angiography)
4. Any lesion more than 3 mm diameter

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants

548

Key exclusion criteria
1. Proposed use of a drug eluting stent (in the study vessel[s])
2. Left Main Stem stenosis
3. Primary Percutaneous Coronary Intervention (PCI) for ST elevation myocardial infarction
4. Steroid therapy within 30-days of study enrolment
5. Contraindication to corticosteroid use
6. Previous inclusion in this study
7. Non-cardiac disease likely to cause death within six months
8. Inter-hospital transfers from Cumbria

Date of first enrolment
01/01/2006

Date of final enrolment
01/01/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The James Cook University Hospital
Middlesbrough
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Sponsor information

Organisation
South Tees Hospitals NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.southtees.nhs.uk/

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Government

Funder Name
South Tees Hospitals NHS Trust (UK) - Cardiothoracic Directorate Research and Development Department

Funder Name
Guidant Corporation (UK)

Funder Name
Cordis Corporation (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	01/08/2016		Yes	No