

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

Submission date 03/10/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 02/08/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 19/05/2016	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

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Additional identifiers

Protocol serial number

CTA number: 22011/0001/001-0001

Study information

Scientific Title

The STARS (STeroids Against Re-Stenosis) trial: the use of peri-procedural oral corticosteroids 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

Study type(s)

Treatment

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(s)

Angiographically documented in-segment re-stenosis.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

The James Cook University Hospital

Middlesbrough

United Kingdom

TS4 3BW

Sponsor information

Organisation

South Tees Hospitals NHS Trust (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

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