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An optical coherence tomography study to determine stent coverage in polymer coated versus bare metal rapamycin eluting stents

Submission date 16/06/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/06/2007	**Overall study status** Completed	
Last Edited 02/12/2010	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
The hypothesis of this study is that there is more complete stent strut coverage in the polymer free rapamycin eluting 'Yukon' stent (Translumina), compared with the durable polymer based rapamycin eluting stent 'Cypher' (Cordis) using optical coherence tomography at 3 months post implantation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval from UK Central Office of Research Ethics Committees (COREC) on 4th October 2006 (ref: 06/Q0404/61)

Study design
Single-centre two-arm randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Coronary artery disease

Interventions
In brief all patients will be undergoing drug eluting intracoronary stent deployment as clinically indicated. Patients will be randomly allocated to receive a Yukon (rapamicin eluting polymer free) or Cypher (rapamicin eluting polymer coated) stent using standard clinical protocols according to the discretion of the implanting cardiologist. Patients will be systematically re-catheterised at 90 days and undergo optical coherence tomography.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Comparison of binary stent strut coverage between the Yukon (rapamicin eluting polymer free) and Cypher (rapamicin eluting polymer coated) groups at 90 day optical coherence tomography.

Secondary outcome measures
Comparison of mean neointimal thickness between the Yukon (rapamicin eluting polymer free) and Cypher (rapamicin eluting polymer coated) groups at 90 day optical coherence tomography.

Overall study start date
20/10/2006

Completion date
01/08/2007

Eligibility

Key inclusion criteria
1. Age 18-75
2. Stable or unstable angina, Non-ST Elevation Myocardial Infarction (NSTEMI) but not ST-Elevation Myocardial Infarction (STEMI; primary Percutaneous Coronary Intervention (PCI) or rescue angioplasty) who have been pain-free for > 24h
3. Single or multiple lesions in a native coronary artery
4. 50-99% diameter stenosis
5. Lesion length 8-28mm (visually estimated)
6. Vessel diameter 2.5-3.5mm (visually estimated)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
Total 40 (20 each arm)

Key exclusion criteria
1. Unprotected left mainstem lesion
2. Ostial lesion
3. Bifurcation lesion requiring side branch intervention
4. Severely calcified lesion that cannot be successfully pre-dilated

5. Marked tortuosity or angulation of target vessel
6. STEMI
7. Left Ventricular (LV) ejection fraction <20%
8. Pregnancy or breast feeding
9. Coexisting comorbidity limiting life expectancy to <24 months
10. Renal impairment with Creatinine (Cr) >200 µmol/L

Date of first enrolment
20/10/2006

Date of final enrolment
01/08/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Harefield Hospital
Harefield
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Sponsor information

Organisation
Royal Brompton and Harefield NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www3.rbht.nhs.uk/

ROR
https://ror.org/02218z997

Funder(s)

Funder type
Not defined

Funder Name
Translumina (Hechingen, Germany)

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	01/05/2009		Yes	No