

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/06/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/12/2010	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

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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 (rapamycin eluting polymer free) or Cypher (rapamycin 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

United Kingdom

UB9 6JH

Sponsor information

Organisation

Royal Brompton and Harefield NHS Trust (UK)

Sponsor details

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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