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The British Bifurcation Coronary Study: Old, New and evolving strategies - A randomised comparison of simple versus complex drug-eluting stenting for bifurcation lesions

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
17/03/2010

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

Contact name
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Contact details
Brighton & Sussex University Hospitals NHS Trust (RSCH)
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BN2 5BE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00351260

Secondary identifying numbers
N0051154079

Study information

Scientific Title

Study objectives
When treating a bifurcation coronary artery lesion is it best to treat the main vessel only, or to stent both the main vessel and the side branch?

Please note that as of 17/03/10 this trial has been updated to include exclusion criteria and secondary outcomes. All updates can be found in the relevant field with the above update date.

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Randomised trial comparing stents either in a simple strategy (provisional T stenting) or a complex strategy (total lesion coverage) and to compare outcomes at nine months

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary end point will be a composite of death, myocardial infarction or target vessel failure at nine months

Secondary outcome measures
Added 17/03/10:
1. Repeat angiography
2. Stent thrombosis

Overall study start date
01/10/2004

Completion date
30/09/2006

Eligibility

Key inclusion criteria
Men and women over 18 presenting with coronary bifurcation lesions > 2.5mm main vessel and 2.25mm side branch.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

Key exclusion criteria
Added 17/03/10:
1. Cardiogenic Shock
2. Acute Myocardial Infarction (MI)
3. Additional type C lesion for Rx platelets <50
4. Left Ventricular Ejection Fraction LVEF <20%

Date of first enrolment
01/10/2004

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Brighton & Sussex University Hospitals NHS Trust (RSCH)
Brighton
United Kingdom
BN2 5BE

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Brighton and Sussex University Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding

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	16/03/2010		Yes	No