

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	<input type="checkbox"/> Prospectively registered
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/03/2010	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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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Contact details

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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

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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