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Xience® or Vision® stent - Management of Angina in the elderly

Submission date	Recruitment status	[_] Prospectively registered
24/02/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/03/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/11/2013	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
version 2.0

Study information

Scientific Title
A multicentre randomised controlled trial of drug-eluting versus bare metal stents in the treatment of patients over 80 years of age with complex coronary artery disease

Acronym
XIMA

Study objectives
The treatment of complex coronary disease causing limiting symptoms of angina with drug-eluting stent (DES) technology will prove superior to bare metal stent (BMS) technology, with respect to a combined endpoint of mortality, myocardial infarction (MI), requirement for target vessel revascularisation and severe haemorrhage, in patients aged 80 or above.

Ethics approval required
Old ethics approval format

Ethics approval(s)
King's college hospital research ethics committee approved on the 27th August 2008 ((ref: 08 /H0808/107)

Study design
Multicentre randomised prospective controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Coronary disease; acute coronary syndromes

Interventions
The treatment is a procedure percutaneous coronary intervention. Patients are randomised to receive either a Drug eluting stent or a Bare metal stent. Both arms are followed up for 1 year.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Combined primary outcome at 1 year
1.1. Death
1.2. Myocardial infarction
1.3. Target Vessel Failure
1.4. Major haemorrhage
2. Procedural cost

Secondary outcome measures
1. Angina status
2. Antianginal tablet prescription (Rx)
3. Procedural
3.1. Procedure success
3.2. Procedure Major Adverse Cardiac Events (MACE)
3.3. In-hospital complications
All secondary outcomes will be measured at 3, 6, 12 months.

Overall study start date
01/10/2008

Completion date
01/10/2011

Eligibility

Key inclusion criteria
1. Age > 80 years
2. Stable angina or acute coronary syndrome
3. Coronary narrowing suitable for stenting that is either =15mm long and/or =3mm diameter.
4. Any lesion with high risk of restenosis eg chronic total occlusion (CTO), bifurcation, severe calcification
5. Any left main stem lesion

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
800

Key exclusion criteria

1. Acute ST-Segment Elevation Myocardial Infarction (STEMI)
2. Cardiogenic shock
3. Platelet count =50 x 109/mm^3
4. Patient life expectancy < 1 year
5. Known allergies to clopidogrel, aspirin, heparin, stainless steel, IV contrast or stent drug elutant
6. Recent major gastrointestinal (GI) haemorrhage (within 3 months)
7. Any previous cerebral bleeding episode
8. Participation in another investigational drug or device study
9. Patient unable to give consent
10. Clinical decision precluding the use of DES

Date of first enrolment
01/10/2008

Date of final enrolment
01/10/2011

Locations

Countries of recruitment
England

Spain

United Kingdom

Study participating centre
The Sussex Cardiac Centre
Brighton
United Kingdom
BN2 5BE

Sponsor information

Organisation
Brighton and Sussex University Hospitals NHS Trust (UK)

Sponsor details
Royal Sussex County Hospital
Eastern Road
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+44 (0)1273 696955
scot.harfield@bsuh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.bsuh.nhs.uk/home/

Funder(s)

Funder type
Industry

Funder Name
Abbott Laboratories Limited (UK)

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	15/04/2014		Yes	No