

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

Submission date 24/02/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 17/03/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 13/11/2013	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

Contact name
Dr Adam de Belder

Contact details
The Sussex Cardiac Centre
Royal Sussex County Hospital
Brighton
United Kingdom
BN2 5BE
+44 (0)1273 696955 x 4897
adam.debelder@bsuh.nhs.uk

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

- 1. Acute ST-Segment Elevation Myocardial Infarction (STEMI)
- 2. Cardiogenic shock
- 3. Platelet count $\leq 50 \times 10^9/\text{mm}^3$
- 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

United Kingdom

England

Spain

Study participating centre

The Sussex Cardiac Centre

Brighton

United Kingdom

BN2 5BE

Sponsor information

Organisation

Brighton and Sussex University Hospitals NHS Trust (UK)

Funder(s)

Funder type

Industry

Funder Name

Abbott Laboratories Limited (UK)

Results and Publications

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