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Nordic-Baltic-British left main revascularisation study

Submission date	Recruitment status	[ ] Prospectively registered
21/05/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/05/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/07/2016	Circulatory System	[ ] Record updated in last year

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
8342

Study information

Scientific Title
Nordic-Baltic-British left main revascularisation study: coronary artery bypass grafting versus drug eluting stent percutaneous coronary angioplasty in the treatment of unprotected left main stenosis

Acronym
NOBLE Study

Study objectives
The purpose of the study is to find the most effective treatment for unprotected left main stenosis (UPLM) disease. The patients will be randomised after the diagnostic angiogram and when both the cardiac surgeons and interventional cardiologists have agreed the patient is suitable for either treatment group.

Patients will be randomised on a 1:1 basis. A registry of all UPLM patients and reasons for inclusion and exclusion will be also documented during the study.

The theory behind the study is that stenting of the left main stem may be of equal efficacy and safety to the current gold standard treatment, which is coronary artery bypass surgery. Coronary artery bypass surgery carries significant periprocedural morbidities so if it is proved that stenting is equivalent or superior, this would represent a good option for patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Brighton East REC approved on the 2nd April 2009 (ref: 09/H1107/08)

Study design
Multicentre randomised interventional treatment 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 the contact details provided in the interventions field below to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
1. Coronary artery bypass surgery
2. Percutaneous coronary angioplasty with drug eluting stent

Follow up length: 60 months
Study entry: single randomisation only

Contact details for patient information sheet:
Cardiac Research Unit
Sussex House 1
Abbey Road
Brighton BN2 1ES
United Kingdom

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Combined endpoint of death, stroke, non-index treatment related myocardioal infarction (MI) and new revascularisation (PCI or CABG) after 2 years
2. Death after 5 years

Secondary outcome measures
1. Combined endpoint of death, stroke and non-index treatment related MI after 1 month and after 1, 2, 3 and 4 years
2. Individual endpoints of death, stroke and non-index treatment related MI after 1 month and after 1, 2, 3, 4 and 5 years
3. New revascularisation by CABG or PCI after 1, 2, 3, 4 and 5 years
4. Death after 10 years
5. Definite stent thrombosis/symptomatic graft occlusion
6. Canadian Cardiovascular Society (CCS) angina score
7. New York Heart Association (NYHA) functional class
8. Duration of admission for index treatment

Overall study start date
19/01/2009

Completion date
01/10/2010

Eligibility

Key inclusion criteria
1. Stable, unstable angina pectoris or acute coronary syndrome (ACS)
2. Significant lesion* of left main coronary artery (LMCA) ostium, mid-shaft and/or bifurcation

and with no more than three additional non-complex** percutaneous coronary intervention (PCI) lesions
3. Patient eligible to be treated by coronary artery bypass graft (CABG) and by PCI
4. Signed informed consent

*Visually assessed diameter stenosis greater than 50% or fractional flow reserve less than 0.80
**Length less than 25 mm, non-CTO, non-2-stent bifurcation, non-calcified and non-tortuous vessel morphology coronary lesion

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Planned sample size: 1200; UK sample size: 200

Key exclusion criteria
1. ST-elevation infarction within 24 hours
2. CABG clearly better treatment option (LMCA stenosis and greater than 3, or complex** additional coronary lesions)
3. Patient is in too high risk for CABG
4. Expected survival less than 1 year
5. Allergy to aspirin, clopidogrel or ticlopidine
6. Allergy to Biolimus

**Length greater than 25 mm, CTO, 2-stent bifurcation, calcified or tortuous vessel morphology coronary lesion

Date of first enrolment
19/01/2009

Date of final enrolment
01/10/2010

Locations

Countries of recruitment
Denmark

England

Finland

Norway

Sweden

United Kingdom

Study participating centre
Brighton and Sussex University Hospitals NHS Trust
Brighton
United Kingdom
BN2 5BE

Sponsor information

Organisation
Brighton and Sussex University Hospitals NHS Trust (UK)

Sponsor details
Royal Sussex County Hospital
Eastern Road
Brighton
England
United Kingdom
BN2 5BE

Sponsor type
Hospital/treatment centre

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

Funder(s)

Funder type
Industry

Funder Name
Biosensors Europe SA (BESA) (Switzerland)

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