

Nordic-Baltic-British left main revascularisation study

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Nina Cooter

Contact details
Brighton and Sussex University Hospitals NHS Trust
Eastern Road
Brighton
United Kingdom
BN2 5BE
-
nina.cooter@bsuh.nhs.uk

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Denmark

Finland

Norway

Sweden

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)

Funder(s)

Funder type

Industry

Funder Name

Biosensors Europe SA (BESA) (Switzerland)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration