ISRCTN59071456 https://doi.org/10.1186/ISRCTN59071456

NO BLEeding excess with antiplatelet treatment with thromboserin during coronary artery bypass grafting (CABG)

Submission date 30/07/2010	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/07/2010	**Overall study status** Stopped	
Last Edited 30/11/2011	**Condition category** 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
6930; RC-PG-0308-10210

Study information

Scientific Title

Acronym
NO BLEeding during CABG (NOBLE 2)

Study objectives
Objective:
To evaluate whether activation of thrombosis by cardiac surgery is modified by means of serotonin 5HT2A receptor antagonism.

Study population:
60 patients with a history of coronary artery disease scheduled for coronary artery bypass grafting (CABG). Patients have clinical and investigative findings of critical coronary artery stenoses requiring revascularisation.

Study design:
Randomised controlled double blind study: patients randomised to placebo or thromboserin 10 mg stat followed by 5 mg twice daily (bd). Study duration is 12 months. The drug supply has MHRA approval.

Please note that as of 25/01/2011 this trial has never started and is currently on hold pending review of the protocol with the sponsor.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved (ref: 08/H0806/91)

Study design
Single centre 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
As approved by REC

Health condition(s) or problem(s) studied
Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
Placebo or thromboserin 10 mg stat followed by 5 mg bd. Total duration of 12 months.

Please note, this trial never started as the objectives were no longer viable.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Thromboserin

Primary outcome measure
Platelet aggregate and thrombus growth

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2009

Completion date
28/02/2011

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
The original protocol, which received ethical and MHRA approval states. All patients requiring cardiac surgery.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Planned sample size: 120

Key exclusion criteria
The original protocol, which received ethical and MHRA approval states.
Patients with bradycardia or bradyarrhythmia, unless drug induced and the drug stopped (e.g. ß-adrenoreceptor antagonists).
Patients treated with serotonin re-uptake inhibitors.

Date of first enrolment
01/01/2009

Date of final enrolment
28/02/2011

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Department of Medicine and Therapeutics,
Aberdeen
United Kingdom
AB25 2ZH

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
Claybrook Centre
37 Claybrook Road
London
England
United Kingdom
W6 8LN

Sponsor type
University/education

Website
http://www3.imperial.ac.uk/

ROR

https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Innovation, Speculation and Creativity (RISC) programme

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?
HRA research summary			28/06/2023	No	No