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

Protocol serial number
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

Study type(s)
Treatment

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(s)
Platelet aggregate and thrombus growth

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

Scotland

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

Sponsor information

Organisation
Imperial College London (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

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