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		
Registration date 30/07/2010	Overall study status Stopped	Statistical analysis plan		
		[_] Results		
Last Edited 0 30/11/2011 0	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

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Contact details

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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. ßadrenoreceptor 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?		
<u>HRA research summary</u>			28/06/2023	No	No		