

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 30/11/2011	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

Prof Mark Noble

Contact details

Department of Medicine and Therapeutics,
University of Aberdeen,
Polwarth Building,
Foresterhill,
Aberdeen
United Kingdom
AB25 2ZH

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)

Primary study design

Interventional

Study design

Single centre randomised interventional treatment trial.

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. β -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,
Aberdeen
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