

The role of platelet activation and inflammation in the associated cardiac complications of surgery for peripheral arterial disease: the benefits of additional clopidogrel therapy

Submission date 16/06/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/06/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/07/2010	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

2005-000960-25

Protocol serial number

2005/R/CAR/04

Study information

Scientific Title

The role of platelet activation and inflammation in the adverse Cardiovascular outcomes of patients undergoing surgery for Critical Limb ISchaemia: a double-blind randomised controlled trial of clopidogrel

Acronym

CCLIS

Study objectives

We hypothesised that in patients undergoing surgical intervention for critical limb ischaemia:

1. Platelet activation would be increased in patients who subsequently develop a post-operative acute coronary syndrome
2. Additional clopidogrel therapy would reduce markers of systemic inflammation and platelet activation

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Fife and Forth Valley Local research Ethics Committee on the 4th April 2005 (ref: 05/S0501/41; Eudract Number: 2005-000960-25).

Study design

Interventional single-centre, prospective double-blind randomised placebo controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Critical limb ischaemia

Interventions

Pre-operative dual anti-platelet therapy versus single anti-platelet therapy. Patients were maintained on aspirin (75 mg/day) and were randomised to clopidogrel (600 mg prior to surgery, and 75 mg daily for three days) or matched placebo.

Total duration of treatment = 4 days (pre-operative loading dose of 600 mg clopidogrel/placebo, plus 75mg/day for 3 days starting on the morning of surgery).

Total duration of follow up = 6 months following surgery.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Clopidogrel

Primary outcome(s)

Markers of in vivo platelet activation (platelet-monocyte aggregates and platelet expression of P-selectin), measured before study drug, after study drug, post-operatively in the recovery room and between 8 am - 10 am on day one following surgery.

Key secondary outcome(s)

1. Markers of myocardial injury (cardiac troponin I [cTn-I]), measured before study drug, after study drug, post-operatively in the recovery room and between 8 am - 10 am on day one following surgery
2. Bleeding outcomes (thrombosis in myocardial infarction [TIMI] and clopidogrel in unstable angina to prevent recurrent events [CURE] classifications); any bleeding events occurring from the time of surgery to hospital discharge
3. Cardiovascular events (acute coronary syndrome, transient ischaemic attack, stroke, death from cardiovascular cause) recorded from time of surgery to hospital discharge, within three months of surgery and within six months of surgery

Completion date

29/02/2008

Eligibility**Key inclusion criteria**

1. Patients aged greater than 45 years, either sex
2. Critical limb ischaemia, defined as the presence of rest pain or skin breakdown, and an ankle-brachial pressure index less than 0.2
3. Scheduled for infra-inguinal bypass, endarterectomy or amputation under general anaesthesia

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Women of child bearing potential
2. Non-atherosclerotic vascular disease
3. Sudden acute limb ischaemia requiring emergency surgery
4. Supra-inguinal or aortic surgery
5. History of acute coronary syndrome within three months
6. History of peptic ulcer disease
7. Previous or current intracranial haemorrhage

8. Bleeding diathesis
9. Uncontrolled hypertension or thrombocytopenia
10. Planned epidural or spinal anaesthesia
11. Hypersensitivity or allergy to thienopyridines
12. Current warfarin or thienopyridine use

Date of first enrolment

01/09/2005

Date of final enrolment

29/02/2008

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

The Chancellors Building

Edinburgh

United Kingdom

EH16 4SU

Sponsor information

Organisation

Lothian Health Board (LHB) (UK)

ROR

<https://ror.org/03q82t418>

Funder(s)

Funder type

Research organisation

Funder Name

British Heart Foundation (UK) (ref: FS/05/038)

Alternative Name(s)

The British Heart Foundation, the_bhf, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

European Society of Vascular Surgery (Denmark)

Funder Name

Royal College of Surgeons of Edinburgh (UK)

Alternative Name(s)

The Royal College of Surgeons of Edinburgh, RCSEd

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Funder Name

Sanofi Aventis (UK) - unrestricted Educational Award

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2010		Yes	No

