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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

Registration date
23/06/2008

Overall study status
Completed

Last Edited
16/07/2010

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
2005-000960-25

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 resaerch 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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 occuring 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

Overall study start date
01/09/2005

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

Age group
Adult

Sex
Both

Target number of participants
100

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
Scotland

United Kingdom

Study participating centre
The Chancellors Building
Edinburgh
United Kingdom
EH16 4SU

Sponsor information

Organisation

Lothian Health Board (LHB) (UK)

Sponsor details
c/o Heather Cubie
49 Little France Crescent
Edinburgh
Scotland
United Kingdom
EH16 4SU

Sponsor type
Hospital/treatment centre

Website
http://www.research.luht.scot.nhs.uk/home.htm

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_bhf, The British Heart Foundation, 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)
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

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?
Results article	results	01/07/2010		Yes	No