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Is cessation of clopidogrel therapy associated with rebound of platelet activity in stable vascular disease patients?

Submission date 10/02/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/04/2009	**Overall study status** Completed	
Last Edited 12/11/2013	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Julie Brittenden

Contact details
Ward 36
Aberdeen Royal Infirmary
Foresterhill
Aberdeen
United Kingdom
AB25 2ZN

Additional identifiers

EudraCT/CTIS number
2007-007638-21

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol 2.1

Study information

Scientific Title
Is cessation of clopidogrel therapy associated with rebound of platelet activity in stable vascular disease patients? - a randomised double-blind placebo-controlled trial

Acronym
CLASP

Study objectives
The primary aim of this clinical trial is to identify whether there is evidence for a "rebound" effect on platelet markers associated with cessation of clopidogrel therapy. We propose to address this in patients with stable cardiovascular disease by means of a mechanistic study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Committee, approved on 07/07/2008 (ref: 08/S0801/87)

Study design
Randomised double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cardiovascular and peripheral vascular disease

Interventions
We aim to test 78 subjects in each treatment arm over a period of 2 years.

Participants will be allocated to either:
I. Clopidogrel (oral) 75 mg daily for 30 days, or
II. Placebo (oral) 75 mg daily for 30 days

On day 31, all participants will stop taking the study drugs but will continue to take their usual medications including aspirin. They will be studied for a further month, testing at 7, 14 and 28 days after stopping clopidogrel or placebo. Total duration of study = 2 months per participant.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Measurement of platelet activation and aggregation, before treatment, on clopidogrel/placebo, and at 7, 14 and 28 days after cessation of clopidogrel/placebo.

Secondary outcome measures
The following inflammatory and procoagulant markers will be assessed before treatment, on clopidogrel/placebo, and at 7, 14 and 28 days after cessation of clopidogrel/placebo:
1. High-sensitivity C-reactive protein (hs-CRP)
2. D-Dimer
3. Soluble CD40 (sCD40) ligand
4. Soluble P-selectin (sP-selectin)

While the primary aim of this study is not to measure clinical outcome, such data will be collected in order to inform a later multi-centre clinical outcome study.

Overall study start date
26/11/2008

Completion date
31/07/2011

Eligibility

Key inclusion criteria
1. Both males and females, age 30-80 years
2. Evidence of chronic atherosclerotic disease - stable coronary heart disease or peripheral arterial disease
3. Already receiving standard secondary prevention therapy for cardiovascular disease, including aspirin therapy and a statin
4. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
156

Key exclusion criteria
1. Known allergy to clopidogrel
2. Contraindications to clopidogrel as listed in the Summary of Product
3. Characteristics for clopidogrel (i.e Hypersensitivity to the active substance or to any of the excipients of the medicinal product, severe liver impairment, active pathological bleeding such as peptic ulcer or intracranial haemorrhage, breast feeding)
Also:
4. History of thrombocytopenia, neutropenia or haematological malignancy
5. Bleeding diathesis
6. Abnormal renal or hepatic function
7. Transfusion of whole blood cells within 14 days prior to randomisation
8. Known or suspected drug or alcohol abuse
9. Clinical symptoms of heart failure
10. Women of child-bearing potential
11. Taking anticoagulant or antiplatelet drugs other than aspirin
12. Participation in another clinical trial of a medicinal product (CTIMP) within preceding 3 months

Date of first enrolment
26/11/2008

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Ward 36
Aberdeen
United Kingdom
AB25 2ZN

Sponsor information

Organisation
Grampian Health Board and University of Aberdeen (UK)

Sponsor details

Research and Development
Foresterhill Annex
Foresterhill
Aberdeen
Scotland
United Kingdom
AB25 2ZN
mmd175@abdn.ac.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nhsgrampian.org

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Charity

Funder Name
Heart Research UK (UK) (ref: RG2555/08/10) - main funder

Funder Name
UK Clinical Research Collaboration (UKCRC) via the Chief Scientist Office (UK)

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	28/01/2014		Yes	No