

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/04/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/11/2013	Condition category Circulatory System	<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

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