

Short TEG: cessation of clopidogrel following insertion of drug-eluting coronary stents

Submission date 23/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/07/2013	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7907

Study information

Scientific Title

An investigation into the effects of cessation of clopidogrel therapy on vascular inflammation and platelet reactivity in patients with drug-eluting coronary stents: is there a "rebound phenomenon"?

Study objectives

The hypothesis of this trial is that cessation of clopidogrel maintenance therapy after 12 months in patients receiving drug-eluting stents is associated with a pro-inflammatory and pro-thrombotic response that offers an explanation for the observed clustering of clinical events, including stent thrombosis, that have been described in the first 90 days after clopidogrel is stopped.

Antiplatelet agents (drugs used to prevent platelets from binding together and forming blood clots) are widely used in the prevention and treatment of cardiovascular disease. Aspirin and clopidogrel are essential antiplatelet drugs required in all patients undergoing percutaneous coronary intervention (PCI) where narrowed arteries are stretched open with balloons and stents to improve the blood supply to the heart. Previous studies have demonstrated a wide range of patient response to antiplatelet agents. Poor responders are at increased risk of complications including potentially fatal stent thrombosis (blood clot forming within the stent), particularly in the period immediately after cessation of clopidogrel. A large observational study has reported a clustering of events, including death and heart attacks within the first 90 days of stopping clopidogrel, raising the possibility of a clopidogrel "rebound" effect. The reason for this effect is unknown and it has been proposed that it may be due to an increase in inflammatory markers and platelet activation following withdrawal of clopidogrel.

The aim of our study is to investigate whether clopidogrel cessation 12 months after PCI causes a rebound proinflammatory and prothrombotic effect. We will investigate the mechanism behind this phenomenon and whether it is related to the lack of synergistic effect of clopidogrel on responses to aspirin when clopidogrel treatment is withdrawn. We will also assess whether the response differs in diabetic patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Southampton and South West Hampshire Research Ethics Committee (A) approved on the 5th November 2009 (ref: 09/H0502/106)

Study design

Randomised interventional screening clinical laboratory study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

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

Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions

Patients are not randomised to any treatment in this trial. All enrolled patients are due to stop dual antiplatelet medication as part of their routine care. This study is assessing the effects of stopping clopidogrel at the end of a routine 12 months course of treatment. Patients are followed up in the study for approximately 7 weeks attending the hospital for 7 blood tests over that time.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Clopidogrel is routinely used for 12 months after drugeluting stent implantation

Secondary outcome measures

Any differences in inflammatory markers, measured at 12 months

Overall study start date

01/01/2010

Completion date

01/11/2010

Eligibility

Key inclusion criteria

1. Aged greater than 18 years, either sex
2. Signed written informed consent
3. Prior percutaneous coronary intervention (PCI) with drugeluting stent implantation and due to stop clopidogrel 12 months after PCI
4. On maintenance dose aspirin 75 mg and clopidogrel 75 mg daily
5. 30 diabetics and 30 nondiabetics

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 60

Key exclusion criteria

1. Aged greater than 85 years
2. On regular nonsteroidal antiinflammatory medication or steroids

Date of first enrolment

01/01/2010

Date of final enrolment

01/11/2010

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Southampton General Hospital

Southampton

United Kingdom

SO16 6YD

Sponsor information**Organisation**

Southampton University Hospitals NHS Trust (UK)

Sponsor details

MRC Environmental Epidemiology Unit

Tremona Road

Southampton

England

United Kingdom

SO16 6YD

Sponsor type

Hospital/treatment centre

Website

<http://www.suht.nhs.uk/home.aspx>

ROR

<https://ror.org/0485axj58>

Funder(s)

Funder type

Industry

Funder Name

Haemonetics Limited (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	01/10/2011		Yes	No