ISRCTN51917813 https://doi.org/10.1186/ISRCTN51917813

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

Submission date	Recruitment status	[_] Prospectively registered
23/04/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/07/2013	Circulatory System	

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 90days 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