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Two different drug regimens in patients undergoing elective percutaneous coronary intervention

Submission date
20/05/2015

Recruitment status
No longer recruiting

Registration date
21/05/2015

Overall study status
Completed

Last Edited
17/08/2020

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Coronary artery disease (CAD) is caused by fatty deposits building up over time in the arteries that supply the heart with blood. The fatty deposits cause the arteries to narrow, eventually reducing the amount of blood that can get to the heart. One of the treatment options for CAD is percutaneous coronary intervention (PCI). In PCI, a balloon is inserted into the artery supplying blood to the heart to open it up where it has narrowed. A small mesh tube called a stent is then left in the artery once the balloon is removed to permanently hold the artery open and allow more blood to flow to the heart. One of the risks of PCI stent insertion, and also in CAD, is the formation of blood clots that can block the arteries, stopping or reducing blood flow and causing a heart attack. Small blood cells called platelets are involved in the formation of the blood clots that cause heart attacks. Antiplatelet drugs (e.g. aspirin) are given to patients with CAD to reduce the risk of a clot forming and causing a heart attack. In a recent large clinical trial (the PLATO study), it was shown that heart attack patients treated with the new antiplatelet drug ticagrelor had fewer heart attacks compared to the current standard drug treatment clopidogrel. The aim of this study is to compare three different treatment strategies for prescribing these antiplatelet drugs to patients with stable CAD following PCI stent surgery.

Who can participate?
Adults with stable CAD on a waiting list for PCI stent implantation.

What does the study involve?
All participants have standard PCI stent surgery. Participants are then randomly allocated into one of three groups. Those in group 1 (intervention group) are given the drug clopidogrel. Those in group 2 (intervention group) are given dose 1 of the drug ticagrelor. Those in group 3 (intervention group) are given dose 2 of the drug ticagrelor. Participants take the medication for 30 days and have blood tests and meet with the research team during that time to assess the effects of each medication strategy.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
University of Sheffield (UK)

When is the study starting and how long is it expected to run for?
June 2015 to December 2016

Who is funding the study?
AstraZeneca UK Limited (UK)

Who is the main contact?
Mrs C Bridge

Contact information

Type(s)
Scientific

Contact name
Mrs Claire Bridge

Contact details
University of Sheffield
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Additional identifiers

ClinicalTrials.gov (NCT)
NCT02327624

Clinical Trials Information System (CTIS)
2014-004783-38

Protocol serial number
18975

Study information

Scientific Title
Study of two regimens of TicagrElor compared to clopidogrel in patients undergoing ELective Percutaneous Coronary Intervention (STEEL PCI)

Acronym
STEEL PCI

Study objectives

Not available at time of registration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ref:14/YH/1274

Primary study design
Interventional

Study design
Randomised interventional treatment study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Atherothrombosis

Interventions
Patients will have their PCI as normal but are randomised to take one of three different medication strategies for 30 days:
1. Clopidogrel
2. Dose 1 ticagrelor
3. Dose 2 ticagrelor

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
1. Ticagrelor 2. Clopidogrel

Primary outcome(s)
Adenosine reuptake measured by blood test.

Key secondary outcome(s)
Not available at time of registration.

Completion date
08/12/2016

Eligibility

Key inclusion criteria
1. Provision of informed consent prior to any study specific procedures
2. Male or female >18 years

3. Previous invasive coronary angiography with plan for PCI with coronary stent implantation for stable coronary artery disease

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
180

Key exclusion criteria
1. Requirement for a chronic total occlusion to be crossed in order for any stent implantation to proceed
2. Plan for coronary angiography with a view to PCI if appropriate (i.e. current coronary anatomy not known)
3. Intention to use platelet function tests or genotyping to guide antiplatelet therapy
4. Known allergy to or intolerance of aspirin, clopidogrel or ticagrelor
5. Treatment with antiplatelet medication apart from aspirin or clopidogrel that cannot be stopped 10 days prior to PCI (e.g. ticagrelor, prasugrel, dipyridamole, ticlopidine, abciximab, tirofiban), for example because of continuing indication
6. Planned treatment or consideration of treatment with oral antiplatelet medication other than aspirin or clopidogrel following PCI
7. Planned use of a glycoprotein IIb/IIIa antagonist for the PCI procedure
8. Myocardial infarction within the past 12 months
9. Current or planned use of an oral anticoagulant (e.g. warfarin, dabigatran, rivaroxaban, apixaban)
10. Previous history of intracranial haemorrhage or other intracranial pathology associated with increased bleeding risk
11. Haemoglobin <100 g/L or other evidence of active bleeding
12. Peptic ulceration documented by endoscopy within the last 3 months unless healing proven by repeat endoscopy
13. History of acute or chronic liver disease (e.g. cirrhosis)
14. Treatment in the last 10 days or requirement for ongoing treatment with a strong CYP3A4 inhibitor or inducer
15. Requirement for ongoing treatment with simvastatin or lovastatin at a dose greater than 40 mg per day
16. Treatment with a CYP3A4 substrate with a narrow therapeutic index (e.g. cyclosporine, quinidine)
17. Endstage renal failure requiring dialysis
18. History of alcohol or drug abuse in the last year

19. Comorbidity associated with life expectancy <1 year
20. Females of childbearing potential unless negative pregnancy test at screening and willing to use effective contraception (i.e. established use of oral, injected or implanted hormonal methods of contraception or placement of an intrauterine device (IUD) or intrauterine system (IUS) or barrier methods of contraception with spermicide or sole male partner with prior vasectomy and confirmed absence of sperm in ejaculate) for the duration of treatment with study medication
21. Any other condition deemed by the investigator to place the patient at excessive risk of bleeding with ticagrelor

Date of first enrolment
08/06/2015

Date of final enrolment
08/12/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Sheffield
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Trust

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
AstraZeneca UK Limited (UK)

Results and Publications

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	21/06/2018	17/08/2020	Yes	No
HRA research summary			28/06/2023	No	No