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Antiplatelet Treatment in Diabetes

Submission date 12/05/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/05/2010	**Overall study status** Completed	
Last Edited 23/06/2020	**Condition category** Nutritional, Metabolic, Endocrine	

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
2009-011907-22

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7863

Study information

Scientific Title

Antiplatelet Treatment in Diabetes

Acronym
DRN 416

Study objectives
Cardiovascular disease is the major cause of death in patients with diabetes. Aspirin is recommended as primary and secondary prevention for cardiovascular disease and it has proven clinical efficacy. However, recent studies suggest it may have limited effectiveness in people with diabetes, which may be dose-related and may be related to blood sugar levels, which are usually raised in diabetes. Clopidogrel may be used as a alternative to aspirin in secondary prevention and Prasugrel is licensed for use in conjunction with aspirin, but not alone. All three are antiplatelet agents but they have differing modes of action. This study will compare the effects of these agents on clot structure and platelet function in people with type 2 diabetes. It will also increase knowledge of the influence varying blood sugar levels have on the effects of these agents.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved, ref: 09/H1307/110

Study design
Single-centre randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Diabetes Research Network; Subtopic: Type 2; Disease: Cardiovascular disease

Interventions
Subjects with type 2 diabetes currently taking aspirin 75 mg. Following a 2-week run in period, they will be randomised to receive either clopidogrel 75 mg or prasugrel 10 mg daily for 4 weeks. Following this they will be switched to receive whichever treatment they did not receive during the first phase. At the end of a further 4 weeks study treatment they will recommence aspirin therapy as before.

Follow-up length: 4 months
Study entry: single randomisation only

Intervention Type
Drug

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
Clopidogrel, prasugrel, aspirin

Primary outcome measure
Comparison of the biochemical efficacy of aspirin, clopidogrel and prasugrel in subjects with type 2 diabetes

Secondary outcome measures
To study the mechanisms of antiplatelet treatment failure in individuals with type 2 diabetes

Overall study start date
01/05/2010

Completion date
30/04/2012

Eligibility

Key inclusion criteria
1. Aged 18 less than 75 years, either sex
2. Type 2 diabetes mellitus
3. Currently taking aspirin 75 mg per day
4. Weight 60 kg or over
5. Must be able to give informed consent and comply with the protocol
7. Using reliable contraception, i.e., oral contraceptive pill, intrauterine device, diaphragm + condom

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Planned sample size: 56; UK sample size: 56

Total final enrolment
56

Key exclusion criteria
1. Prior treatment with clopidogrel or prasugrel
2. Previous or current treatment with warfarin or non-steroidal inflammatory drugs (NSAID)
3. A history of acute coronary syndrome within 3 months of recruitment
4. Any history of coagulation or bleeding disorder, neoplastic disease, deep vein thrombosis, pulmonary embolism
5. Any previous or current upper gastrointestinal pathology
6. Any history of cerebral vascular accident or transient ischaemic attack
hypersensitiviy to the active substance (i.e., clopidogrel or prasugrel) or any of the excipients
7. Active pathological bleeding
8. Any individual found to have abnormal liver function (measured by alanine aminotransferase [ALT] greater than 3 times upper limit of normal) or abnormal thyroid function will be excluded at this time and offered further investigation
9. Weight less than 60 kg
10. Inadequate contraception (as described in inclusion criteria)
11. Pregnant and lactating women. In the unlikely event of pregnancy during the study, the individual will be immediately withdrawn.

Date of first enrolment
01/05/2010

Date of final enrolment
30/04/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leeds
Leeds
United Kingdom
LS2 9JT

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
Woodhouse Lane
Leeds
England
United Kingdom
LS2 9JT

Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Industry

Funder Name
Eli Lilly and Company Limited (UK) (ref: H7T-BP-0003)

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?
Basic results			23/06/2020	No	No
HRA research summary			28/06/2023	No	No