

Antiplatelet Treatment in Diabetes

Submission date 12/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/05/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/06/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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
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 an 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
7. Hypersensitivity to the active substance (i.e., clopidogrel or prasugrel) or any of the excipients
8. Active pathological bleeding
9. 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
10. Weight less than 60 kg
11. Inadequate contraception (as described in inclusion criteria)
12. 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/024mrx33>

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