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# Antiplatelet Treatment in Diabetes

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

**Clinical Trials Information System (CTIS)**
2009-011907-22

**Protocol serial number**
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

## Study type(s)
Treatment

## 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(s)

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

### Key secondary outcome(s))
To study the mechanisms of antiplatelet treatment failure in individuals with type 2 diabetes

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### 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**
United Kingdom

England

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

# Sponsor information

**Organisation**
University of Leeds (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

## 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 |