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# Impact of single versus double dose acetylsalicylic acid on platelet function in patients with type 2 diabetes

**Submission date**
31/01/2012

**Recruitment status**
No longer recruiting

**Registration date**
31/01/2012

**Overall study status**
Completed

**Last Edited**
08/02/2016

**Condition category**
Nutritional, Metabolic, Endocrine

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

## Plain English summary of protocol

Background and study aims?
People with type 2 diabetes have an increased risk of heart disease, possibly partially explained by research findings that platelets (the small fragments of cells that help blood to clot) in diabetic patients are over-active, allowing their blood to clot more easily and possibly block blood vessels to the heart and other organs. Aspirin (ASA), a medicine that reduces platelet activity, is recommended for diabetic patients who already have heart disease to reduce the likelihood of a further heart attack or stroke. Whether aspirin reduces the risk of a first heart attack or stroke in diabetic patients is unclear.
This study will examine whether single (100 mg) or double (200 mg) doses of ASA can reduce platelet function successfully in diabetic patients without heart disease and will determine whether the double dose works better when given as a single dose or 100mg twice daily.

Who can participate?
Patients without a history of heart disease or stroke between the age of 18-75 years who have type 2 diabetes controlled by diet or stable doses of anti-hyperglycaemic medication.

What does the study involve?
The study is designed in a way that that each participant will receive each treatment for 2 week periods in random order as follows:
ASA 100 mg once daily
ASA 200 mg once daily
ASA 100 mg twice daily
Platelet function will be assessed by blood tests at the beginning and at the end of each treatment period. There will be a 2-week break between treatments to ensure that the ASA effects have been washed out before beginning the next treatment period.
The study will last approximately 12 weeks for each patient and involve a maximum of 5 study visits to the Churchill Hospital and 3 telephone contacts from the research team.

Where is the study run from?
The Clinical Research Unit (CRU) at the Oxford Centre for Diabetes, Endocrinology & Metabolism

(OCDEM), Churchill Hospital Oxford, will perform this study which is sponsored by the University of Oxford.

What are the possible benefits and risks of participating?
There are no direct benefits of taking part in this initial study but the results could help researchers to design a large-scale study that may lead to future important medical findings such as identifying the best way to treat patients with type 2 diabetes in order to prevent heart attacks and strokes.
The risks of participating in this study are limited. Aspirin has been associated with minor bleeding, such as a nose-bleed or bruising. Severe bleeding with aspirin occurs very rarely. The health of each study patient will be monitored during the study and the study medication will be stopped should there be any cause for concern.

When is the study starting and how long is it expected to run for?
November 2011 to January 2013

Who is funding the study?
It is funded by the British Heart Foundation charity.

Who is the main contact?
The Diabetes Trial Unit
trg@dtu.ox.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Prof Rury Holman

### Contact details
Diabetes Trials Unit
Oxford Centre for Diabetes, Endocrinology and Metabolism
Old Road, Headington
Oxford
United Kingdom
OX3 7LJ
+44 1865 857255
trg@dtu.ox.ac.uk

# Additional identifiers

### EudraCT/CTIS number
2011-003123-35

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
10708

# Study information

### Scientific Title
Impact of single versus double dose acetylsalicylic acid on platelet function in patients with type 2 diabetes: a randomised crossover study

### Acronym
ASP

### Study objectives
The high residual platelet reactivity commonly seen in aspirin-treated patients with type 2 diabetes mellitus might be overcome by giving higher or more frequent doses of aspirin. The study will evaluate the impact of single, double or twice daily dosing regimens on platelet function in patients with type 2 diabetes mellitus who do not have cardiovascular disease.

More details can be found at http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=10708

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
South East London Research Ethics Committee 3 First MREC approval date 07/09/2011, 11/LO /1200

### Study design
Randomised; Interventional; Design type: Treatment

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### 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
Diabetes (type 2)

### Interventions

Acetylsalicylic acid (ASA), Three two-week treatment regimens will be applied in randomized order in participant individuals, namely:
1. ASA 100mg once daily
2. ASA 200mg once daily
3. ASA 100mg twice daily

There will be a two-week washout period between each treatment period.; Follow Up Length: 3 month(s); Study Entry : Registration and One or More Randomisations

### Intervention Type
Other

### Phase
Phase IV

### Primary outcome measure
Change in platelet reactivity between baseline and the end of each treatment period.; Timepoint (s): Measures of platelet reactivity taken at baseline and at the end of each treatment period

### Secondary outcome measures
A variety of COX-1 dependent and independent platelet function tests.; Timepoint(s): Platelet function tests carried out at baseline and at the end of each treatment period

### Overall study start date
30/11/2011

### Completion date
18/01/2013

## Eligibility

### Key inclusion criteria
Inclusion criteria as of 08/02/2016:
1. Have type 2 diabetes (defined according to the European Association for the Study of Diabetes (EASD) guidelines)
2. Are aged between 18 years and 75 years
3. Have not had a coronary event or other indication requiring ASA
4. Are on diet alone or stable doses of antihyperglycaemic medication, i.e. the type of medication or dose used has not been changed for at least 3 months
5. Have HbA1c levels ≤ 10.0%
6. Have triglycerides ≤ 2mmol/l

Original inclusion criteria:
1. Have type 2 diabetes (defined according to the European Association for the Study of Diabetes (EASD) guidelines)
2. Are aged between 18 years and 55 years
3. Have not had a coronary event or other indication requiring ASA
4. Are on diet alone or stable doses of antihyperglycaemic medication, i.e. the type of medication or dose used has not been changed for at least 3 months
5. Have HbA1c levels ≤ 8.0%
6. Have triglycerides ≤ 2mmol/l

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 24; UK Sample Size: 24

### Key exclusion criteria
1. Have cardiovascular disease, including coronary heart disease, stroke and peripheral artery disease
2. Have been taking any dose of ASA, non-steroidal anti-inflammatory drugs, any antiplatelet or antithrombotic drugs within the last 30 days
3. Have a history of peptic ulcer disease
4. Are treated with insulin
5. Have high blood pressure (>150 mmHg systolic or >100 mmHg diastolic
6. Have a known bleeding disorder
7. Have a known gastrointestinal disorder
8. Have evidence of severe hepatic disease or ALT >3 times the upper limit of normal at screening
9. Have evidence of severe renal dysfunction or estimated glomerular filtration rate (eGFR) <40ml/min/1.73m2 at screening
10. Have a contraindication to ASA, such as allergy or active bleeding
11. Have a planned intervention or surgery in the next 3 months
12. Are pregnant or lactating women
13. Are currently taking part, or have completed, an Investigational Medicinal Product (IMP) trial within the last 3 months
14. Are unsuitable for the trial as decided by a clinician

### Date of first enrolment
30/11/2011

### Date of final enrolment
18/01/2012

## Locations

### Countries of recruitment
England

United Kingdom

**Study participating centre**
**Diabetes Trials Unit**
Oxford
United Kingdom
OX3 7LJ

# Sponsor information

**Organisation**
University of Oxford

**Sponsor details**
Research Services
Clinical Trials and Research Governance
Joint Research Office
Block 60
Churchill Hospital, Headington
Oxford
England
United Kingdom
OX2 6HE

**Sponsor type**
University/education

**Website**
http://www.admin.ox.ac.uk/researchsupport/ctrg/

**ROR**
https://ror.org/052gg0110

# Funder(s)

**Funder type**
Charity

**Funder Name**
British Heart Foundation (BHF) (UK) Grant Codes: PG/11/29/28852

**Alternative Name(s)**
the_bhf, The British Heart Foundation, BHF

**Funding Body Type**
Private sector organisation

### Funding Body Subtype
Trusts, charities, foundations (both public and private)

### Location
United Kingdom

# 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 | 01/02/2016 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |