The Prevention Of Progression of Asymptomatic Diabetic Arterial Disease (a multicentre study)

| Submission date 17/10/2000 | Recruitment status No longer recruiting | Prospectively registered | | |
|----------------------------|--|------------------------------|--|--|
| | | [] Protocol | | |
| Registration date | Overall study status | [] Statistical analysis plan | | |
| 17/10/2000 | Completed | [X] Results | | |
| Last Edited 20/10/2008 | Condition category Nutritional, Metabolic, Endocrine | 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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers G9534799

Study information

Scientific Title

Acronym POPADAD study

Study objectives

The aim of the trial is to evaluate whether aspirin and antioxidant therapy, either separately or together, are more effective than placebo in reducing the development of vascular events.

Ethics approval required Old ethics approval format

Ethics approval(s) LREC/10/10/1996 MREC/98/0/104 11/02/1999

Study design Double blind randomised and controlled, 2 x 2 factorial design

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Not specified

Study type(s) Not Specified

Participant information sheet

Health condition(s) or problem(s) studied Diabetes with asymptomatic arterial disease

Interventions Aspirin 100 mg/day and antioxidant therapy, separately or together/placebo

Intervention Type Drug

Phase Not Specified

Drug/device/biological/vaccine name(s) Aspirin and antioxidant therapy

Primary outcome measure

There are two hierarchical primary endpoints sought in this study: 1. Coronary heart disease and stroke death plus non-fatal stroke and myocardial infarction and above ankle amputation for critical limb ischaemia 2. Coronary heart disease death and fatal stroke

Secondary outcome measures

- 1. All cause mortality
- 2. Non-fatal myocardial infarction

3. Other vascular events including coronary and peripheral arterial bypass surgery and/or angioplasty, development of angina, claudication, transient ischaemic attack or development of critical limb ischaemia

Overall study start date

01/08/1997

Completion date

31/12/2006

Eligibility

Key inclusion criteria

1. Participants will be both Insulin-Dependent Diabetes Mellitus (IDDM) and Non Insulin-Dependent Diabetes Mellitus (NIDDM) patients of either sex, 40+ years of age 2. All patients will have ankle brachial pressure index (ABPI) of less than 0.98

Participant type(s)

Patient

Age group

Adult

Sex Both

Target number of participants 1600

Key exclusion criteria

- 1. Participants taking regular aspirin, antioxidant therapy
- 2. Evidence of symptomatic vascular disease
- 3. Serious physical illness such as cancer which may curtail life expectancy
- 4. Psychiatric illness (reported by GP)
- 5. Congenital heart disease
- 6. Pregnancy

Date of first enrolment

01/08/1997

Date of final enrolment

31/12/2006

Locations

Countries of recruitment Scotland

United Kingdom

Study participating centre Department of Medicine Dundee United Kingdom DD1 9SY

Sponsor information

Organisation University of Dundee (UK)

Sponsor details Research & Innovations Services University of Dundee Dundee Scotland United Kingdom DD1 4HN +44 (0)1382 344000 university@dundee.ac.uk

Sponsor type University/education

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

ROR https://ror.org/03h2bxq36

Funder(s)

Funder type Research council Funder Name Medical Research Council (UK)

Alternative Name(s) Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type Government organisation

Funding Body Subtype National government

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 | 16/10/2008 | | Yes | No |