

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

Submission date

17/10/2000

Recruitment status

No longer recruiting

Registration date

17/10/2000

Overall study status

Completed

Last Edited

20/10/2008

Condition category

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ 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

Protocol serial number

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

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

Scotland

Study participating centre

Department of Medicine

Dundee

United Kingdom

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Sponsor information

Organisation

University of Dundee (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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?
Results article	Results	16/10/2008		Yes	No