

# 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

**Contact name**

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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, 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?
<a href="#">Results article</a>	Results	16/10/2008		Yes	No