

Randomised controlled trial of bezafibrate in patients with lower extremity arterial disease (LEAD)

Submission date 06/04/2000	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 06/04/2000	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 30/11/2017	Condition category Circulatory System	☐ 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
E185/124

Study information

Scientific Title

Randomised controlled trial of bezafibrate in patients with lower extremity arterial disease (LEAD)

Acronym

LEADER trial

Study objectives

Bezafibrate reduces primary end point by 30%.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cardiovascular

Interventions

Bezafibrate/control

Intervention Type

Drug

Drug/device/biological/vaccine name(s)

Bezafibrate

Primary outcome(s)

Coronary heart disease events and strokes combined

Key secondary outcome(s)

Fatal and non-fatal coronary events separately

Completion date

30/09/2001

Eligibility**Key inclusion criteria**

Males with LEAD (no upper or lower age limit)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Male

Key exclusion criteria

1. Already on lipid-modifying agent
2. Renal or hepatic disease (including raised creatinine concentration)
3. Unstable angina; malignant disease
4. Serious intercurrent illness

Date of first enrolment

01/05/1992

Date of final enrolment

30/09/2001

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

London School of Hygiene & Tropical Medicine

Non-communicable Disease Epidemiology Unit

London

United Kingdom

WC1E 7HT

Sponsor information**Organisation**

Medical Research Council (MRC) (UK)

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	design and intermediary results	23/07/2001		Yes	No
Results article	results	23/07/2001		Yes	No
Results article	results	16/11/2002		Yes	No
Results article	results	16/11/2002		Yes	No