

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

Submission date 06/04/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/04/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/11/2017	Condition category Circulatory System	<input type="checkbox"/> 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

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Cardiovascular

Interventions

Bezafibrate/control

Intervention Type

Drug

Drug/device/biological/vaccine name(s)

Bezafibrate

Primary outcome measure

Coronary heart disease events and strokes combined

Secondary outcome measures

Fatal and non-fatal coronary events separately

Overall study start date

01/05/1992

Completion date

30/09/2001

Eligibility

Key inclusion criteria

Males with LEAD (no upper or lower age limit)

Participant type(s)

Patient

Age group

Not Specified

Sex

Male

Target number of participants

1568 men recruited through 85 practices

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

England

United Kingdom

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)

Sponsor details

20 Park Crescent
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clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

<http://www.mrc.ac.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, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

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	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