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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/04/2000	**Overall study status** Completed	
Last Edited 30/11/2017	**Condition category** Circulatory System	

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
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Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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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

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	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