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Does angioplasty offer benefit over best medical treatment and supervised exercise training in mild to moderate intermittent claudication (MIMIC) patients?

Submission date
09/09/2005

Registration date
11/11/2005

Last Edited
14/07/2010

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MREC 03/08/7

Study information

Scientific Title

Acronym
MIMIC

Study objectives
The aim of the MIMIC trials is to assess the adjuvant benefit of percutaneous transluminal angioplasty (PTA) in patients with Mild to Moderate Intermittent Claudication (MIMIC). All patients will receive best medical treatment, including advice to stop smoking and receive supervised exercise training for 6 months. 340 patients from 10 centres will be randomly allocated to receive angioplasty or not into one of two trials, one for aorto-iliac disease and another for femoro-popliteal disease and followed up for 2 years. It is expected that the MIMIC trials will show whether either aorto-iliac or femoro-popliteal angioplasty are of adjuvant benefit to best medical treatment and exercise therapy in terms of Absolute Walking Distance (AWD) as the primary endpoint, and secondly in terms of both specific and generic health related quality of life (HRQL) measures and, if beneficial, the cost effectiveness of the additional intervention.

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
Intermittent claudication; peripheral vascular disease

Interventions
Supervised exercise therapy versus supervised exercise therapy and PTA.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
AWD at 2 years compared to baseline.

Secondary outcome measures
1. Generic and disease specific quality of life questionnaires
2. Cost economics
3. Patency

Overall study start date
01/02/2003

Completion date
31/01/2007

Eligibility

Key inclusion criteria
1. Patients with stable mild to moderate intermittent claudication
2. Patients satisfying the criteria of the Edinburgh Claudication Questionnaire
3. Patients suitable for aorto-iliac or femoro-popliteal PTA after duplex mapping or diagnostic arteriography
4. Ankle Brachial Pressure Indices (ABPI) <0.9 or >0.9 with a positive stress test i.e. a fall of >30 mmHg following a treadmill test at 4 km/h, 10 degree slope for 1 min

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
340

Key exclusion criteria
1. Patients with intermittent claudication too mild for patient or doctor to consider PTA
2. Patients with intermittent claudication severe enough to merit consideration of bypass surgery
3. Patients with critical ischaemia i.e. absolute Doppler pressure <50 mmHg, or presence of

ulcers or gangrene with a Doppler pressure >50 mmHg
4. Patients with ankle/brachial pressure index (ABPI) >0.9 with a negative stress test who could have sciatica or very mild peripheral arterial disease (insignificant arterial disease)
5. Patients with musculoskeletal, cardiac or any other concomitant disease that renders consideration for supervised exercise inappropriate

Date of first enrolment
01/02/2003

Date of final enrolment
31/01/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dept Vascular Surgery
London
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Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
Clinical Research Office
Imperial College London
G02 Sir Alexander Fleming Building
South Kensington Campus
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England
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Sponsor type
University/education

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Industry

Funder Name
Camelia Botnar Arterial Research Foundation (UK)

Funder Name
Bard Ltd (UK)

Funder Name
Boston Scientific Ltd (UK)

Funder Name
Cook UK Ltd (UK)

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	results	01/12/2008		Yes	No