

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/11/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/07/2010	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Roger Greenhalgh

Contact details
Dept Vascular Surgery
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF
+44 (0)208 846 7316
r.greenhalgh@imperial.ac.uk

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

AWD at 2 years compared to baseline.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre
Dept Vascular Surgery
London
United Kingdom
W6 8RF

Sponsor information

Organisation
Imperial College London (UK)

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

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