

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

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|--|---|---|
| Submission date 09/09/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 11/11/2005 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 14/07/2010 | 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

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

United Kingdom

W6 8RF

Sponsor information

Organisation

Imperial College London (UK)

Sponsor details

Clinical Research Office

Imperial College London

G02 Sir Alexander Fleming Building

South Kensington Campus

London

England

United Kingdom

SW7 2AZ

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 |