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A comparison of upper-limb and lower-limb exercise training in patients with intermittent claudication (IC)

Submission date 24/08/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/10/2005	**Overall study status** Completed	
Last Edited 28/07/2010	**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

PG/2000042

Study information

Scientific Title

Study objectives
Upper-limb aerobic exercise training will be as effective as lower-limb aerobic exercise training for evoking symptomatic improvements in patients with symptomatic peripheral arterial disease (PAD).

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)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Peripheral arterial disease.

Interventions
Upper- versus lower-limb aerobic exercise training. Supervised training sessions were held twice weekly for 6 weeks with arm cranking or leg cranking.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Walking performance (claudication distance and maximum walking distance).

Secondary outcome measures
1. Upper- and lower-limb aerobic exercise capacity
2. Disease-specific and generic quality of life measures
3. Blood markers of cardiovascular disease risk

Overall study start date
01/10/2000

Completion date
31/12/2005

Eligibility

Key inclusion criteria
Patients with stable intermittent claudication were recruited from the Sheffield Vascular Institute at the Northern General Hospital, Sheffield, UK. The clinical diagnosis of PAD was established using the patients history and a physical examination, and was confirmed by the Doppler assessment of ankle-brachial pressure index (ABPI), a non-invasive reliable measure of lower-extremity hemodynamics, in accordance with current UK medical practice.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
104

Key exclusion criteria
Patients experiencing symptoms of IC for less than 12 months, or reporting a significant change in walking ability within this time period were considered to have unstable disease and were, as a consequence, excluded. Patients were also excluded if they exhibited features of critical ischemia, had undergone a re-vascularization procedure within the previous 12 months, or if initial assessment established that they suffered from severe arthritis (i.e. if they were unable to walk unaided or perform either upper- or lower limb cranking exercise due to joint pain), severe lumbar spine disease or unstable cardiorespiratory conditions (i.e. unstable blood pressure, recent electrocardiographic changes or acute myocardial infarction, unstable angina, third-degree heart block, acute congestive heart failure and severe respiratory conditions).

Date of first enrolment
01/10/2000

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Sport and Exercise Science
Sheffield
United Kingdom
S10 2BP

Sponsor information

Organisation
Sheffield Hallam University (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www.shu.ac.uk

ROR
https://ror.org/019wt1929

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (UK) - (Grant number: PG/2000042)

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

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	results	01/12/2005		Yes	No
Results article	results	01/02/2006		Yes	No
Results article	results	01/05/2008		Yes	No