

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/10/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/07/2010	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

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

City Campus

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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