Effects of exercise on health and quality of life in peripheral arterial disease

Submission date	Recruitment status	Prospectively registered
06/07/2009	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
11/09/2009	Completed	Results
Last Edited	Condition category	[] Individual participant data
11/09/2009	Circulatory System	 Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Exercise and intermittent claudication: health outcomes and cost effectiveness in a single centre randomised controlled trial

Study objectives

Peripheral arterial disease (PAD) is a manifestation of generalised atherosclerotic disease in which the arterial lumen becomes progressively narrowed by atherosclerotic plaques. This gradual narrowing of the lumen results in reduced blood flow to the tissues causing pain on exercise, relieved by rest (intermittent claudication). PAD is a marker for significant cardiovascular and cerebrovascular events (e.g., myocardial infarction [MI], stroke). Despite its prevalence and associated cardiovascular risk factors, patients with PAD are treated less intensively than patients with coronary artery disease. Several studies have demonstrated that exercise programmes result in significant improvements in walking distances but the long-term benefits and effects on subsequent cardiovascular morbidity and mortality are unknown. The aim of this study is:

- 1. To assess the long-term effects on risk factor modification
- 2. To assess the long-term effects on quality of life
- 3. To assess the long-term effects on fatal and non-fatal events
- 4. To compare the cost effectiveness over time between the current management strategy and exercise intervention

Ethics approval required

Old ethics approval format

Ethics approval(s)

Beaumont Hospital Ethics Committee approved in November 2005

Study design

Single centre randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Intermittent claudication

Interventions

Intervention Group:

Participants participate in a twice-weekly supervised exercise programme for 12 weeks. The total duration of the programme is one hour, including warm-up and cool down periods.

Participants undertake a 10 minute warm-up consisting of gentle walking, stepping and stretching exercises (upper limb, lower limb and trunk). Participants then exercise for 30 - 40 minutes using a range of exercise equipment: treadmill, stepper, elliptical trainer, recumbent cycle ergometer and upper/lower limb cycle ergometer. Participants are encouraged to exercise at an intensity of 70 - 80% heart rate maximum or 70 - 80% of their exercise stress test maximum. On the treadmill participants are encouraged to continue exercising until they are unable to continue due to leg pain (generally a maximum of 10 minutes). Participants are then permitted to rest until the pain subsided and then encouraged to recommence exercising. The exercise level is set at an intensity that produced moderate claudication pain within 5 minutes. Exercise is progressed by increasing resistance and/or time.

Control Group: Usual care.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Recorded at baseline, 12 weeks and 1 year:

- 1. Risk factors:
- 1.1. Diastolic and systolic blood pressure
- 1.2. Height
- 1.3. Weight
- 1.4. Waist circumference
- 1.5. Ankle/brachial index (ABI) at rest and exercise
- 1.6. Laboratory test results: fasting blood glucose, triglycerides, cholesterol, plasma fibrinogen, high-sensitivity C-reactive protein (hs-CRP), glycosylated haemoglobin (HbA1C)
- 2. Generic health status: 36-item short form health survey questionnaire (SF36)
- 3. Disease-specific health status: Intermittent Claudication Questionnaire (ICQ)
- 4. Functional capacity: Walking Impairment Questionnaire (WIQ)
- 5. Physical activity: peripheral Arterial Disease Physical Activity Recall Questionnaire (PAD-PAR)

Key secondary outcome(s))

Recorded at baseline, 12 weeks and 1 year:

- 1. Health status valuation EQ5D
- 2. Morbidity and mortality data from hospital paper and computer records

Completion date

01/06/2010

Eligibility

Key inclusion criteria

- 1. Fontaine Stage II: intermittent claudication diagnosed by history of leg pain on exercise relieved by rest, classified by presence/absence of pulse/s, site of pain, ankle/brachial index (ABI) less than 0.9 at rest and/or decrease in ankle pressure by 15 mmHg or more after standard treadmill test (standard incline and constant speed)
- 2. Stable disease x 3 months
- 3. Residing within the geographical catchment area of the hospital
- 4. Aged 48 83 years, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

- 1. Fontaine Stage I (ambulation not limited by claudication)
- 2. Fontaine Stage III (rest pain)
- 3. Fontaine Stage IV (focal necrosis)
- 4. Co-existing clinical condition, which precluded participation in exercise programme including:
- 4.1. Unstable cardiorespiratory disease
- 4.2. Neurological/orthopaedic limitation to exercise
- 4.3. Poorly controlled hypertension
- 4.4. Active major medical problem including but not limited to cancer, renal/liver disease
- 4.5. Dementia
- 4.6. Poorly controlled diabetes mellitus
- 4.7. Abdominal aortic aneurysm
- 4.8. Myocardial infarction within the previous 6 months
- 5. Participants with acute onset or within the first months of onset of claudication (due to fluctuation in symptoms)
- 6. Revascularisation procedure/surgery within previous 6 months

Date of first enrolment

01/12/2006

Date of final enrolment

01/06/2010

Locations

Countries of recruitment

Ireland

Study participating centre Royal College of Surgeons in Ireland

Dublin Ireland 2

Sponsor information

Organisation

Royal College of Surgeons in Ireland (Ireland)

ROR

Funder(s)

Funder type

Research organisation

Funder Name

Royal College of Surgeons in Ireland (Ireland) - Research Committee

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration