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

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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)

Secondary outcome measures
Recorded at baseline, 12 weeks and 1 year:
1. Health status valuation - EQ5D
2. Morbidity and mortality data from hospital paper and computer records

Overall study start date
01/12/2006

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

Age group
Adult

Sex
Both

Target number of participants
46

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
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Sponsor information

Organisation
Royal College of Surgeons in Ireland (Ireland)

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Sponsor type
Research organisation

Website
http://www.rcsi.ie/

ROR
https://ror.org/01hxy9878

Funder(s)

Funder type
Research organisation

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

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