Mild to moderate claudication: the costeffectiveness of supervised exercise programmes in patient management.

Submission date	Recruitment status Stopped	Prospectively registered		
25/04/2003		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
25/04/2003 Last Edited	Stopped Condition category	[X] Results		
		☐ Individual participant data		
21/08/2009	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

EudraCT/CTIS number

IRAS number

 ${\bf Clinical Trials. gov\ number}$

Secondary identifying numbers

HTA 99/22/08

Study information

Scientific Title

Acronym

EXACT

Study objectives

The main objectives of the study are as follows:

- 1. To compare outcomes for the following treatment strategies for patients with mild to moderate claudication:
- 1.1. Angioplasty (i.e. status quo treatment)
- 1.2. Supervised exercise programme
- 1.3. Exercise and lifestyle advice only (control)
- 2. To measure the cost of each strategy, including treatment and subsequent health care costs, over 3 years
- 3. To compare costs and short-term to medium-term (6 months 3 year) outcomes in different patient groups

Please note that, as of 21/08/2009, the start date of this trial has been updated from 1/09/2001 to 01/12/2001.

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)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Cardiovascular diseases: peripheral arterial disease

Interventions

- 1. Angioplasty (i.e. status quo treatment)
- 2. Supervised exercise programme.
- 3. Exercise and lifestyle advice only (control)

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/12/2001

Completion date

31/05/2005

Eligibility

Key inclusion criteria

Patients with claudication

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/12/2001

Date of final enrolment

31/05/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Department of Psychology

Worcester United Kingdom WR2 6AJ

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Quarry House
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LS2 7UE
+44 (0)1132 545 843
Sheila.Greener@doh.gsi.gov.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/en/index.htm

ROR

https://ror.org/03sbpja79

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (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	01/01/2006		Yes	No