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

|                      | Prospectively registered      |
|----------------------|-------------------------------|
| Stopped              | ☐ Protocol                    |
| Overall study status | Statistical analysis plan     |
| Stopped              | [X] Results                   |
| Condition category   | ☐ Individual participant data |
| Circulatory System   | Record updated in last year   |
|                      | Stopped  Condition category   |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Brian McCloskey

#### 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 Quarry Hill Leeds United Kingdom 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              |