ISRCTN78288224 https://doi.org/10.1186/ISRCTN78288224

# Neurogenic claudication physiotherapy trial

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 01/04/2008 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 26/06/2008 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 08/10/2013 | Musculoskeletal Diseases | |

**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**
18183

## Study information

## Scientific Title
Physiotherapy for neurogenic claudication: a randomised trial of older adults in a primary care-based physiotherapy service

## Study objectives
Condition-specific physiotherapy rehabilitation is more effective than advice and education alone in the treatment of neurogenic claudication.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics approval received from the Leeds Central Ethics Committee on the 22nd February 2008 (ref: 08/H1313/1).

## 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
Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Degenerative lumbar spinal stenosis

## Interventions
Advice/education-only arm:
Receive a one-off treatment session consisting of advice and education about lumbar spinal stenosis (pathology, diagnosis, prognosis, management) based on patient information provided by the American Rheumatology Society. Telephone access to a physiotherapist for advice will be available if needed over subsequent 6 weeks.

Advice/education plus physiotherapy rehabilitation:
As above plus between 4 and 6 sessions with a physiotherapist over subsequent 6 week period. Treatment consisting of exercise programme (lumbar flexion, core stability, fitness exercises) to be carried out daily, monitored and adjusted by treating physiotherapist.

## Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
Swiss Spinal Stenosis Score (Zurich Claudication Score) symptom severity scale at eight weeks.

### Secondary outcome measures
At twelve months follow-up:
1. Oswestry Disability Index
2. Visual Analogue Pain Scale (VAS)
3. General Well-Being Index

### Overall study start date
02/04/2008

### Completion date
31/03/2011

## Eligibility

### Key inclusion criteria
1. Patients aged 50 or over, either sex
2. Symptoms of neurogenic claudication (walking-induced lower limb symptoms which are relieved in sitting/flexion)
3. Limitation of normal walking tolerance due to symptoms of neurogenic claudication

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
76

### Key exclusion criteria
1. Clearly defined radicular symptoms (sciatica)
2. Cognitive impairment or medical conditions preventing understanding or participation in trial
3. Symptoms requiring urgent surgical or other intervention (red flags, such as acute equina syndrome)

### Date of first enrolment
02/04/2008

### Date of final enrolment
31/03/2011

# Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
### Academic Unit of Musculoskeletal Disease
Leeds
United Kingdom
LS7 4SA

# Sponsor information

### Organisation
University of Leeds (UK)

### Sponsor details
c/o Clare Skinner
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### Sponsor type
University/education

### Website
http://www.leeds.ac.uk/

### ROR
https://ror.org/024mrxd33

# Funder(s)

### Funder type
Charity

**Funder Name**
Arthritis Reseach Campaign (ARC) (UK) (grant ref: 18183)

# 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 | 30/09/2013 | | Yes | No |