

# Neurogenic claudication physiotherapy trial

<b>Submission date</b> 01/04/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/06/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/10/2013	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## 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

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

Faculty of Medicine & Health Research Manager

Research Support Unit

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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 Research 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?
<a href="#">Results article</a>	results	30/09/2013		Yes	No