

Neurogenic claudication physiotherapy trial

Submission date 01/04/2008	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 26/06/2008	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 08/10/2013	Condition category Musculoskeletal Diseases	☐ 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

Protocol serial number

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).

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Swiss Spinal Stenosis Score (Zurich Claudication Score) symptom severity scale at eight weeks.

Key secondary outcome(s)

At twelve months follow-up:

1. Oswestry Disability Index
2. Visual Analogue Pain Scale (VAS)
3. General Well-Being Index

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Academic Unit of Musculoskeletal Disease

Leeds

United Kingdom

LS7 4SA

Sponsor information

Organisation

University of Leeds (UK)

ROR

<https://ror.org/024mrxd33>

Funder(s)

Funder type

Charity

Funder Name

Arthritis Research Campaign (ARC) (UK) (grant ref: 18183)

Results and Publications

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