

Developing better care for the elderly patients with walking disability due to degenerative lumbar spine stenosis

Submission date 29/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/01/2021	Condition category 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0626176966

Study information

Scientific Title

Developing better care for the elderly patients with walking disability due to degenerative lumbar spine stenosis

Study objectives

Not provided at time of registration

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)

Not specified

Study type(s)

Quality of life

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

Musculoskeletal Diseases: Degenerative lumbar spine stenosis

Interventions

Walking tolerance will be measured with and without a stick.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Shuttle walking crossover test: difference in walking tolerance (measured in metres) between SWT with walking stick and SWT without walking stick. Each shuttle is 10 metres, thus the number of completed shuttles counted by the investigator will be multiplied by 10 to provide an outcome measure in metres.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2006

Completion date

01/09/2008

Eligibility

Key inclusion criteria

1. Patients 65 and over
2. Unilateral or bilateral neurogenic claudication (NC), ie exercise induced leg pain on walking, relieved in sitting
3. Patient reported limitation of walking tolerance due to symptoms of NC

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

20

Key exclusion criteria

1. Cognitive impairment preventing full understanding or participation in the study
2. Evidence of medical conditions such as hip/leg pathology or peripheral vascular disease, which may mimic NC or prevent participation in a shuttle walking test
3. Severe or worsening neurological status
4. Signs/symptoms of cauda equina compression, inflammatory joint disease, signs/symptoms of sinister pathology (unexplained weight loss, unremitting/night-time pain, history of cancer), which may require urgent surgical opinion. This will be determined through subjective and objective examination of patients by the recruiting researcher at the point of screening
5. Exclusion criterion for Home Trial Pilot phase only: previous use of walking aid

Date of first enrolment

01/01/2006

Date of final enrolment

01/09/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Wharfedale Hospital

Otley

United Kingdom

LS21 2LY

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall

London

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+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Bradford South and West Primary Care Trust (UK), NHS R&D Support Funding

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	06/01/2021	Yes	No