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A Comparison Between Two Physical Therapy Treatment Programs for Subjects with Lumbar Spinal Stenosis (LSS): A Randomized Clinical Trial

Submission date
11/10/2005

Recruitment status
No longer recruiting

Registration date
25/10/2005

Overall study status
Completed

Last Edited
16/05/2013

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
FWH20010030H

Study information

Scientific Title

Study objectives
Subjects receiving a program that includes manual physical therapy, exercise, and a body weight supported ambulation program will achieve superior outcomes compared to the subjects receiving flexion based exercise, sub-therapeutic ultrasound, and a treadmill walking program without body weight support.

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Lumbar Spinal Stenosis

Interventions
Individualized Rehabilitation Group: Manual physical therapy, exercise, body weight supported treadmill ambulation

Traditional Rehabilitation Group: Flexion exercises, level treadmill ambulation, and placebo ultrasound

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Global Rating of Change

Secondary outcome measures
Modified Oswestry, Treadmill Test, Swiss Spinal Stenosis Scale, NPRS, Patient Specific Functional Scale

Overall study start date
01/06/2001

Completion date
30/01/2005

Eligibility

Key inclusion criteria
1. Age greater than or equal to 50 years and eligible for military health care
2. Magnetic resonance imaging (MRI) findings consistent with LSS (evidence of compression of lumbar spinal nerve root(s) by degenerative lesions of the facet joint, disc, and/or ligamentum flavum)
3. Chief complaint of pain in the low back, buttock and/or lower extremity(s)
4. Rates sitting as a better position with respect to symptom severity than standing or walking
5. Lives within one hour of either Brooke Army Medical Center or Wilford Hall Medical Center
6. Can attend regular physical therapy appointments for six weeks (2 appointments per week) and three examination appointments (baseline, end of treatment, and 1 year after completion of treatment)
7. Sufficient English reading and language skills and mental capability to complete pain and functional assessment questionnaires

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Severe vascular, pulmonary or coronary artery disease which limits ambulation (as determined by the referring physician, the specialist, or the therapist)
2. Other orthopedic conditions or physical impairments of unrelated nature which would limit ambulation or prevent the subject from fully participating in any other aspect of the rehabilitation exercises (as determined by the referring physician, the specialist, or the therapist)
3. Previous spinal surgery
4. History of spinal tumors, spinal infection, or lumbar vertebral fractures other than spondylolisis or spondylolisthesis

5. Inability to have an MRI scan of the lumbar spine. As with any standard MRI scan, the MRI clinic staff will determine if a subject may or may not complete the test. The following conditions may exclude a patient from being able to have the MRI scan: pacemaker, biomedical implants, a history of metal work or hobbies including metal work, cochlear implants, metal in the eye, claustrophobia, obesity (over 440 lbs).

Date of first enrolment
01/06/2001

Date of final enrolment
30/01/2005

Locations

Countries of recruitment
United States of America

Study participating centre
3485 W 115th Ave
Westminster
United States of America
80031

Sponsor information

Organisation
Wilford Hall Medical Center (USA)

Sponsor details
59 CRES
2200 Bergquist Drive, Bld 4430
Lackland AFB
San Antonio
United States of America
TX 78236
+1 210 292 7924
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/025m0q735

Funder(s)

Funder type
Charity

Funder Name
Orthopaedic Section of the American Physical Therapy Association ($10,000); US Air Force Surgeons General ($10,000)

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	15/10/2006		Yes	No
Results article	results	01/10/2012		Yes	No