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The effectiveness of motorised lumbar traction in the management of lumbosacral nerve root pain

Submission date	Recruitment status	[ ] Prospectively registered
25/01/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/03/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/04/2008	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jacqueline Gracey

Contact details
School of Health Sciences
University of Ulster
Shore Road
Newtownabbey
United Kingdom
BT37 0QB
+44 (0)28 9036 8284
jh.gracey@ulster.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives
To compare the effectiveness of two treatment protocols (manual therapy, exercise and advice with or without traction) in the management of acute/subacute Low Back Pain (LBP) with nerve root involvement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local ethics committee at the University Ulster in March 2004.

Study design
Pragmatic single-blind 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
Low back pain

Interventions
Group 1: Manual therapy, exercise and advice
Group 2: Manual therapy, exercise, advice and continous lumbar traction

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

1. Roland Morris Disability Questionnaire
2. McGill pain questionnaire
3. Acute low back pain screening questionnaire
4. Short Form health survey 36

Secondary outcome measures
1. Visual analogue scale - pain
2. Medication diary
3. Percentage improved - subjective patient score

Overall study start date
01/03/2004

Completion date
26/02/2005

Eligibility

Key inclusion criteria
1. Aged 18 to 65 years of age (male and female), presenting with acute/sub-acute LBP with accompanying radiculopathy
2. Nerve root was identified by the presence of:
a. dermatomal pain distribution radiating below the knee (one or both limbs)
b. sharp/severe quality, often worse in the leg than back (leg pain threshold of 3/10 on Visual Analogue Scale [VAS])
With at least one of the following signs and symptoms:
c. pins and needles in the distal dermatome (where this was present patients with leg pain were accepted even if not extending below the knee)
d. increased pain in the leg on coughing, sneezing or straining
e. neurological deficit, i.e., decreased muscle strength/sensory loss/reflex loss
f. positive straight leg raise test stretch, i.e., limb pain reproduced on test
3. Acute/sub acute LBP, defined as LBP of less than 12 weeks duration, or a recurrent episode with a pain free period of at least three months prior to the onset of this episode. Only one study has considered recovery rates with sciatica and reported that both back and leg pain decreased, on average, by 69%, and disability decreased by 57% within one month from onset. Current physiotherapy practice would suggest that treatment begins as soon as possible; therefore patients were accepted after four weeks of onset of leg pain
4. Able to attend for physiotherapy two to three times a week for four to six weeks
5. Patients were literate with English as their first language

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
30

Key exclusion criteria
1. Previous spinal surgery
2. Formal therapeutic or medical intervention within the last three months (e.g., epidural injection, facet joint block, physiotherapy etc..,)
3. Co-existing conditions (anklyosing spondolytitis, rheumatoid arthritis, spinal stenosis [diagnosed], spondolythesis, recent spinal fracture, spinal tumor or a patient where secondary metastases was suspected)
4. Concomitant severe medical problem preventing participation in the trial (cardiac condition, respiratory conditions, neurological disorder or organ disease)
5. Long term oral steroid intake (due to the risk of osteoporosis)
6. Current anti-coagulant therapy or blood clotting disorders
7. Pregnancy
8. History of major psychiatric illness
9. Roland Morris disability questionnaire score of below four, and/or a VAS score of less than three on a ten point scale for leg pain (to avoid floor effects)

Date of first enrolment
01/03/2004

Date of final enrolment
26/02/2005

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
School of Health Sciences
Newtownabbey
United Kingdom
BT37 0QB

Sponsor information

Organisation
University of Ulster (UK)

Sponsor details
c/o Dr Annette Harte
School of Health Sciences
Shore Road
Newtownabbey
Northern Ireland
United Kingdom
BT37 0QB
+44 (0)28 9036 6650
aa.harte@ulster.ac.uk

Sponsor type
University/education

Website
http://www.ulster.ac.uk

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type
University/education

Funder Name
University of Ulster (UK)

Alternative Name(s)
University of Ulster, Ulster, Ulster Uni, UU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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	29/11/2007		Yes	No