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Prospective, Randomised Blinded trial to compare outcome following lumbar discectomy and DYNESYS® dynamic distraction stabilisation for symptomatic isolated contained single level lumbar disc prolapse.

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/10/2015	Surgery	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0188149742

Study information

Scientific Title
Prospective, Randomised Blinded trial to compare outcome following lumbar discectomy and DYNESYS® dynamic distraction stabilisation for symptomatic isolated contained single level lumbar disc prolapse.

Study objectives
To determine whether there is a significant difference in outcome between patients undergoing lumbar discectomy and those undergoing DYNESYS® dynamic distraction stabilisation for patients who have symptomatic isolated, contained single level lumbar disc prolapse confirmed on MRI scanning, causing straight leg sciatica.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Surgery: Discectomy

Interventions
RCT comparing outcome following lumbar discectomy and DYNESYS® dynamic distraction stabilisation.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
Change in functional scores and 10 point visual analogue pain scores following surgery. Carried out pre-operatively as a baseline and then at 6 weeks, 6 months, 1 year and 2 years.

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/08/2007

Eligibility

Key inclusion criteria
Patients awaiting surgery for isolated single level lumbar disc prolapse seen on MRI with straight leg sciatica aged 25-60 years old.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Patients with
1. other spinal pathology
2. previous spinal surgery
3. Cauda Equina syndrome
4. severe neurological dysfunction
5. very large prolapses

Date of first enrolment
01/08/2004

Date of final enrolment
01/08/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Chorley and South Ribble Hospital
Chorley
United Kingdom
PR7 1PP

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Lancashire Teaching Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration