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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Surgery: Discectomy

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

Intervention Type

Procedure/Surgery

Phase
Not Specified

Primary outcome measure
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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2004

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

Age group
Adult

Sex
Both

Target number of participants
50 participants to be recruited.

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
England

United Kingdom

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

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+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
Hospital/treatment centre

Funder Name
Lancashire Teaching Hospitals NHS Trust (UK)

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