

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 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/10/2015	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr S Ghalayini

Contact details
Orthopaedics
Chorley and South Ribble Hospital
Preston Road
Chorley
United Kingdom
PR7 1PP

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

Study design

Randomised controlled trial

Primary study design

Interventional

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