

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

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 27/10/2015	<b>Condition category</b> 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