

# Lumbosacral fusion study

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/10/2019	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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 John O'Dowd

**Contact details**  
Spinal Disorder Unit  
University Hospital NHS Trust  
D Floor  
West Block  
Queen's Medical Centre  
Nottingham  
United Kingdom  
NG7 2UH  
+44 (0)115 924 9924  
abc@email.com

## Additional identifiers

**Protocol serial number**  
940139

## Study information

**Scientific Title**  
Lumbosacral fusion study

**Study objectives**

The main objective of this study is to measure the difference in outcome when internal fixation techniques are used to augment the spinal fusion.

**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**

Spinal conditions, lumbosacral joint fixation

**Interventions**

1. Standard posterior lumbosacral fusion without instrumentation, using corticocancellous autograft from the patient's own iliac crest
2. An identical operation will be performed, with the addition of pedicle screw fixation system

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Not provided at time of registration

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

31/01/1998

**Eligibility****Key inclusion criteria**

200 patients admitted to the Spinal Surgery Unit for L5-S1 and L4-S1 fusion for back pain and one of the following diagnostic groups will be entered into the trial:

1. Discogenic back pain
2. Lumbar spondylolysis
3. Degenerative spondylolisthesis

4. Isthmic spondylolisthesis
5. Segmental instability
6. Degenerative scoliosis
7. Failed decompressive surgery

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Patients who have predominantly root symptoms
2. Patients who have had previous fusion or stabilisation surgery
3. Patients who are aged over 60

**Date of first enrolment**

01/02/1995

**Date of final enrolment**

31/01/1998

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre****Spinal Disorder Unit**

Nottingham

United Kingdom

NG7 2UH

**Sponsor information****Organisation**

NHS R&D Regional Programme Register - Department of Health (UK)

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

NHS Executive Trent (UK)

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

#### **IPD sharing plan summary**

Not provided at time of registration