

# Chemonucleolysis or manipulation for lumbar disc herniation?

<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> 22/02/2008	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**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**  
ND0020 T367 Burton R&D

# Study information

## Scientific Title

### Study objectives

The purpose of this study is to compare the effects of two treatment modalities available for lumbar disc herniation. The principle aim of the project is to ascertain which, if either, treatment is superior in terms of reducing symptoms/disability, and the relative cost effectiveness/patient satisfaction. The treatments to be studied are chemonucleolysis and osteopathic manipulation. Despite the choice of a well defined low back pathology for this trial, it may be that some 'types' of patient respond better to one or other of the treatments; strenuous attempts will be made to identify any such categories. The benefits to the NHS will be the determination of the more cost-effective treatment for this condition. Should the result favour manipulation, there will be the potential for reduction both of therapeutic costs and of orthopaedic waiting lists.

### 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

### Health condition(s) or problem(s) studied

Lumbar disc herniation

### Interventions

1. Chemonucleolysis
2. Osteopathic manipulation

### Intervention Type

Other

### Phase

Not Specified

**Primary outcome measure**

1. Symptoms/disability and the relative cost effectiveness/patient satisfaction.
2. Pain (back and leg) and disability

**Secondary outcome measures**

Therapeutic failure

**Overall study start date**

02/01/1994

**Completion date**

31/12/1998

## **Eligibility**

**Key inclusion criteria**

Patients with lumbar disc herniation

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

40

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

02/01/1994

**Date of final enrolment**

31/12/1998

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Spinal Research Unit**  
Huddersfield  
United Kingdom  
HD1 2SP

## **Sponsor information**

### **Organisation**

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

### **Sponsor details**

The Department of Health  
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.doh.gov.uk>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

NHS Executive Northern and Yorkshire (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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Results	01/06/2000		Yes	No