# Randomised, double-blind and controlled trial of lumbar microdiscectomies and laminectomies comparing post-operative course and results over one year with and without post-operative glucocorticosteroids.

Submission date 30/09/2005	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>
Last Edited 24/08/2015	<b>Condition category</b> Surgery	<ul> <li>Individual participant data</li> <li>Record updated in last year</li> </ul>

**Plain English summary of protocol** Not provided at time of registration

## **Contact information**

**Type(s)** Scientific

**Contact name** Mr Nicholas Brooke

#### Contact details

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## Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

#### Secondary identifying numbers N0231139989

## Study information

#### Scientific Title

Randomised, double-blind and controlled trial of lumbar microdiscectomies and laminectomies comparing post-operative course and results over one year with and without post-operative glucocorticosteroids.

#### **Study objectives**

Does post-operative glucocorticosteroids alter post-operative outcome after simple lumbar spine surgery?

#### **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: Lumbar

#### Interventions

Patients pre-selected for appropriate surgery from surgical waiting list will be approached at the time of consenting to be entered into therapeutic trial. One additional injection post-op vs standard practice.

#### Intervention Type Drug

#### Phase

Not Applicable

**Drug/device/biological/vaccine name(s)** Glucocorticosteroids

**Primary outcome measure** 1. Oswestry disability score 2. Short form 36

**Secondary outcome measures** Not provided at time of registration

**Overall study start date** 14/03/2005

**Completion date** 01/04/2006

## Eligibility

**Key inclusion criteria** 50 patients from surgical waiting list aged 21-70 years

Participant type(s) Patient

**Age group** Adult

**Sex** Both

**Target number of participants** 50

#### Key exclusion criteria

Although extremely uncommon, if a patient had a lumbar or caudal epidural using glucocorticosteroid post operatively, they would be excluded from the trial.

Date of first enrolment 14/03/2005

Date of final enrolment 01/04/2006

## Locations

Countries of recruitment

England

United Kingdom

**Study participating centre Southampton General Hospital** Southampton United Kingdom SO16 6YD

### 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** Government

**Funder Name** Southampton University Hospitals NHS Trust (UK), NHS R&D Support Funding

### **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