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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
1. Oswestry disability score
2. Short form 36

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/04/2006

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration