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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

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
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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