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Controlled trial of microdiscectomy for lumbar disc herniation

Submission date	Recruitment status	[ ] Prospectively registered
25/04/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/04/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/05/2016	Musculoskeletal Diseases	[ ] 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
HTA 93/09/17

Study information

Scientific Title
Controlled trial of microdiscectomy for lumbar disc herniation

Study objectives
The UK has one of the lowest rates for lumbar disc surgery in the western world. A robust randomised controlled trial, incorporating a health economic analysis, is needed, considering the lack of evidence about clinical outcome and cost effectiveness, particularly in the medium and long term. Microdiscectomy, the standard surgical procedure, will be compared to conservative management. The study will be based in two neurosurgical departments, both leading centres for disc surgery.
Follow-up will be at 3, 6, 12, 18 and 24 months, incorporating outcome measures of proven reliability and validity. The objectives of this project at to:
1. establish the efficacy and cost-effectiveness of surgical management for this patient group
2. to evaluate costs to health care purchasers of surgical and conservative management. A supplementary study will undertake follow-up at 3, 4, and 5 years, although funding is not being applied for at this stage.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Musculoskeletal diseases: Spinal conditions

Interventions
Please note that, as of 14 January 2008, the anticipated end date of this trial has been updated from 31 March 2001 to 30 June 2002.

Interventions:
Microdiscectomy, the standard surgical procedure, will be compared to conservative management.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/07/1996

Completion date
30/06/2002

Eligibility

Key inclusion criteria
Not provided at time of registration.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration.

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/07/1996

Date of final enrolment
30/06/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Neurosurgery
Bristol
United Kingdom
BS16 1LE

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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