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Cervical disc replacement versus inter-body cage for the treatment of spondylotic disease: a randomised, prospective double-blind clinical trial

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
08/06/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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
N0209121271

Study information

Scientific Title
Cervical disc replacement versus inter-body cage for the treatment of spondylotic disease: a randomised, prospective double-blind clinical trial

Study objectives
Is the Bryan disc a better alternative than traditional discectomy and fusion for the treatment of cervical spondylotic disease?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised prospective double-blind clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Musculoskeletal Diseases: Spondylotic disease

Interventions
Surgery, followed by clinical outcome measures and quality of life score.

Intervention Type
Procedure/Surgery

Primary outcome(s)
SF-36, Neck disease Index, Myelopathy Disability Index, Visual Analogue Scale

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

Completion date
01/06/2008

Eligibility

Key inclusion criteria
Patients having cervical discectomy and insertion of cervical disc replacement

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/06/2003

Date of final enrolment
01/06/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal National Orthopaedic Hospital NHS Trust
Stanmore
United Kingdom
HA7 4LP

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Royal National Orthopaedic Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration