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

Submission date	Recruitment status	Prospectively registered
12/09/2003	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Completed	☐ Results
Last Edited	Condition category	Individual participant data
08/06/2017	Musculoskeletal Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Study design

Randomised prospective double-blind clinical trial

Primary study design

Interventional

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

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No Yes