

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

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/06/2017	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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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## 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