

# 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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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### **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 to request a patient information sheet

### **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 measure**

SF-36, Neck disease Index, Myelopathy Disability Index, Visual Analogue Scale

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/06/2003

**Completion date**

01/06/2008

## **Eligibility**

**Key inclusion criteria**

Patients having cervical discectomy and insertion of cervical disc replacement

**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**

01/06/2003

**Date of final enrolment**

01/06/2008

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Royal National Orthopaedic Hospital NHS Trust**  
Stanmore  
United Kingdom  
HA7 4LP

## **Sponsor information**

### **Organisation**

Department of Health (UK)

### **Sponsor details**

Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

### **Sponsor type**

Government

### **Website**

<http://www.doh.gov.uk>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

Royal National Orthopaedic Hospital NHS Trust (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