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# A double blind randomised controlled crossover trial of radiofrequency annuloplasty for the treatment of low back pain

| 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 |
| 28/10/2016 | 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**
Dr Simon Dolin

**Contact details**
Pain Service
St Richards Hospital
Spitalfield Lane
Chichester
United Kingdom
PO19 4SE
+44 (0)1243 788122
Simon.Dolin@rws-tr.nhs.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N0213112412

# Study information

### Scientific Title
A double blind randomised controlled crossover trial of radiofrequency annuloplasty for the treatment of low back pain

### Study objectives
To evaluate clinical results of patients treated with radiofrequency annuloplasty, which is used to relieve discogenic pain in the lumbar spine

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Double blind randomised controlled crossover trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Musculoskeletal Diseases: Low back pain

### Interventions
Treatment group will have radiofrequency annuloplasty. Placebo group same protocol but no lesioning performed - RF generator on test mode.

### 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
01/03/2002

### Completion date
07/03/2007

## Eligibility

### Key inclusion criteria
1. 16-70 years at first assessment
2. Moderate/severe discogenic pain
3. Oswestry disability index 20% +
4. Failed 6 months conservative treatment
5. No previous disc surgery at symptomatic levels; Body Mass Index (BMI) average or overweight range
6. Loss of disc height not >50% of normal level on Magnetic Resonance Imaging (MRI) or X-ray
7. Max two level pathology on MRI scan confirmed by discography

### Participant type(s)
Patient

### Age group
Adult

### 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
01/03/2002

### Date of final enrolment
07/03/2007

## Locations

### Countries of recruitment
England

United Kingdom

**Study participating centre**
**Pain Service**
Chichester
United Kingdom
PO19 4SE

# 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 West Sussex 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