

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

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 12/09/2003	Overall study status Completed	☐ Protocol
Last Edited 28/10/2016	Condition category Musculoskeletal Diseases	☐ 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

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

Primary study design

Interventional

Study design

Double blind randomised controlled crossover trial

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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**

United Kingdom

England

Study participating centre**Pain Service**

Chichester

United Kingdom

PO19 4SE

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Royal West Sussex Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration