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

Submission date
12/09/2003

Registration date
12/09/2003

Last Edited
28/10/2016

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] 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

Study design
Double blind randomised controlled crossover trial

Primary study design
Interventional

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