ISRCTN42725861 https://doi.org/10.1186/ISRCTN42725861

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

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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