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Chemonucleolysis or manipulation for lumbar disc herniation?

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/02/2008	Musculoskeletal Diseases	

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
ND0020 T367 Burton R&D

Study information

Scientific Title

Study objectives
The purpose of this study is to compare the effects of two treatment modalities available for lumbar disc herniation. The principle aim of the project is to ascertain which, if either, treatment is superior in terms of reducing symptoms/disability, and the relative cost effectiveness/patient satisfaction. The treatments to be studied are chemonucleolysis and osteopathic manipulation. Despite the choice of a well defined low back pathology for this trial, it may be that some 'types' of patient respond better to one or other of the treatments; strenuous attempts will be made to identify any such categories. The benefits to the NHS will be the determination of the more cost-effective treatment for this condition. Should the result favour manipulation, there will be the potential for reduction both of therapeutic costs and of orthopaedic waiting lists.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled 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
Lumbar disc herniation

Interventions
1. Chemonucleolysis
2. Osteopathic manipulation

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
1. Symptoms/disability and the relative cost effectiveness/patient satisfaction.
2. Pain (back and leg) and disability

Secondary outcome measures
Therapeutic failure

Overall study start date
02/01/1994

Completion date
31/12/1998

Eligibility

Key inclusion criteria
Patients with lumbar disc herniation

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
40

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
02/01/1994

Date of final enrolment
31/12/1998

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Spinal Research Unit
Huddersfield
United Kingdom
HD1 2SP

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/06/2000		Yes	No