ISRCTN98524302 https://doi.org/10.1186/ISRCTN98524302

Lumbosacral fusion study

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	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/10/2019	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
940139

Study information

Scientific Title
Lumbosacral fusion study

Study objectives
The main objective of this study is to measure the difference in outcome when internal fixation techniques are used to augment the spinal fusion.

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)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Spinal conditions, lumbosacral joint fixation

Interventions
1. Standard posterior lumbosacral fusion without instrumentation, using corticocancellous autograft from the patient's own iliac crest
2. An identical operation will be performed, with the addition of pedicle screw fixation system

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/1995

Completion date
31/01/1998

Eligibility

Key inclusion criteria
200 patients admitted to the Spinal Surgery Unit for L5-S1 and L4-S1 fusion for back pain and one of the following diagnostic groups will be entered into the trial:
1. Discogenic back pain
2. Lumbar spondylolysis
3. Degenerative spondylolisthesis
4. Isthmic spondylolisthesis
5. Segmental instability
6. Degenerative scoliosis
7. Failed decompressive surgery

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Patients who have predominantly root symptoms
2. Patients who have had previous fusion or stabilisation surgery
3. Patients who are aged over 60

Date of first enrolment
01/02/1995

Date of final enrolment
31/01/1998

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Spinal Disorder Unit
Nottingham
United Kingdom
NG7 2UH

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 Trent (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