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Spine stabilisation trial

Submission date 25/10/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/10/2000	**Overall study status** Completed	
Last Edited 30/07/2009	**Condition category** 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
G9431172

Study information

Scientific Title

Study objectives
To compare the outcome of surgical stabilisation (spinal fusion) with a special non-operative rehabilitation in patients with chronic low back pain considered suitable for 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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic low back pain

Interventions
1. Surgical stabilisation (spinal fusion)
2. Special non-operative rehabilitation

Follow-up: 6,12 months, 2 years post randomisation

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The two primary measures at 24 months included a back pain specific questionnaire and a standardised walking test. The Oswestry low back pain disability index is scored from 0% (no disability) to 100% (totally disabled or bedridden) and designed to assess limitations of various activities of daily living. The shuttle walking test is a standardised, progressive, maximal test of walking speed and endurance.

Secondary outcome measures
1. The short form 36 general health questionnaire (SF-36) includes 35 items summarised in two measures related to physical and mental health. Each scale ranges from 0 (worst health state) to 100 (best health state). The summary measures are transformed to give a population mean of 50 (SD 10). The SF-36 is recommended as an outcome assessment for spinal disorders because it provides strong psychometric support and extensive normative data.
2. Psychological assessment: we used the distress and risk assessment method (DRAM), which includes the modified Zung depression index and somatic perception questionnaire, to assess anxiety and depression.
3. Complications: we recorded the intraoperative use of anaesthetic agents, implants; radiological investigations; complications of surgery and any adverse effects of rehabilitation; postoperative complications, implant failure and repeat surgery and personal items and devices purchased by the patient because of lower back pain. Work status was monitored. We recorded 'obvious pseudoarthrosis' only where it was clear to the treating surgeon that fusion had failed and that this was a problem to the patient.

Overall study start date
01/06/1996

Completion date
31/12/2004

Eligibility

Key inclusion criteria
1. Patients who were candidates for surgical stabilisation of the spine were eligible if the clinician and patient were uncertain which of the study treatment strategies was best.
2. Patients had to be aged between 18 and 55, with more than a 12 month history of chronic low back pain (with or without referred pain) and irrespective of whether they had had previous root decompression or discectomy.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Patients were ineligible if the surgeon considered that any medical or other reasons made one of the trial interventions unsuitable.
2. These included infection or other comorbidities (inflammatory disease, tumours, fractures),

psychiatric disease, inability or unwillingness to complete the trial questionnaires, or pregnancy.
3. If patients had had previous surgical stabilisation surgery of the spine they were also excluded.

Date of first enrolment
01/06/1996

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nuffield Orthopaedic Centre
Oxford
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Sponsor information

Organisation
Medical Research Council (MRC) (UK)

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Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	28/05/2005		Yes	No