

Spine stabilisation trial

Submission date 25/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/10/2000	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/07/2009	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

United Kingdom

OX3 7LD

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

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clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

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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