

Flexible or solid stabilisation for lumbar spondylosis? A randomised controlled trial - Stage 1 - Feasibility Study

Submission date 30/09/2004	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 03/11/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 09/11/2010	Condition category Musculoskeletal Diseases	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Alan Breen

Contact details
IMRCI-AECC
13-15 Parkwood Road
Bournemouth
United Kingdom
BH5 2DF
+44 (0)1202 436275
imrci.abreen@aecc.ac.uk

Additional identifiers

Protocol serial number
04/04

Study information

Scientific Title

Acronym

FleSS

Study objectives**Rationale:**

There have been no clinical trials of the new flexible stabilisation, versus the old rigid stabilisation surgery for the large subgroup of chronic back patients who have lumbar spondylosis pain. Furthermore, there has previously been no assessment tool with which to explain the clinical biomechanics of any kind of stabilisation. Therefore, we wish to conduct a feasibility study for randomised controlled trial of rigid, versus flexible (DYNESYS) lumbar spine stabilisation using both patient-assessed and objective biomechanical outcomes.

Objectives

To conduct a feasibility study to inform the working methods and number of subjects needed for a single-blind randomised controlled trial to

1. Compare the effectiveness of flexible (DYNESYS) with posterolateral fusion with pedicle screws and graft (PLF) and
2. Seek explanatory and predictive models for clinical outcomes using an objective spinal motion imaging assessment (OSMIA) at instrumented and adjacent levels

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Lumbar spondylotic back pain

Interventions

DYNESYS flexible posterolateral stabilisation (Intervention) versus Posterolateral fusion (PLF) with pedicle screws and graft

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

ODQ = Oswestry Disability Questionnaire

Key secondary outcome(s)

1. SF36
2. Pain Scale
3. Health Transitions scale
4. Target and adjacent segment motion characteristics

Completion date

30/03/2006

Eligibility**Key inclusion criteria**

Subjects: Patients with severe chronic low back pain of at least 1 year's duration attributed to either post-discectomy pain or primary disc degeneration below L3 in whom conservative treatment has been ineffective and who elect to have spine stabilisation surgery.

Inclusion Criteria:

1. Age 25-65
2. Willing to participate
3. Back pain without radiculopathy and attributable to lumbar spondylosis
4. Conservative therapy tried and failed
5. Elect lumbar stabilisation (1 or 2 level, L3 downward)
6. Suitable for DYNESYS or standard posterolateral fusion (PLF) with pedicle screws and graft using a standardised procedure
7. Oswestry >30

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. Mental illness (except mild depression)
2. No prior conservative therapy
3. Pathology such as fracture, infection, neoplasm
4. Poor understanding of English
5. Spinal stenosis
6. Spondylolisthesis
7. >2 level procedure required
8. Radicular pain
9. Litigation or compensation pending

Date of first enrolment

01/04/2005

Date of final enrolment

30/03/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

IMRCI-AECC

Bournemouth

United Kingdom

BH5 2DF

Sponsor information

Organisation

Zimmer Ltd (UK)

ROR

<https://ror.org/00mke2t69>

Funder(s)

Funder type

Industry

Funder Name

Zimmer Ltd (UK)

Results and Publications

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	15/10/2009		Yes	No