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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/11/2004	**Overall study status** Completed	
Last Edited 09/11/2010	**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
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

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

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 measure
ODQ = Oswestry Disability Questionnaire

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

Overall study start date
01/04/2005

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

Age group
Not Specified

Sex

Not Specified

Target number of participants
30 Added 09/10/10: only 10 patients were recruited and the study ended ended 01/04/08.

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. Spondyolisthesis
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
England

United Kingdom

Study participating centre
IMRCI-AECC
Bournemouth
United Kingdom
BH5 2DF

Sponsor information

Organisation
Zimmer Ltd (UK)

Sponsor details
The Courtyard
Lancaster Place
South Marston Park
Swindon

United Kingdom
SN3 4FP

Sponsor type
Industry

ROR
https://ror.org/00mke2t69

Funder(s)

Funder type
Industry

Funder Name
Zimmer Ltd (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	15/10/2009		Yes	No