prospective follow-up of focal Bone Mineral Density changes in the inter-transverse fusion mass after instrumented single-level posterolateral lumbar spine fusion

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Observational invasive

Summary

ID

NL-OMON33026

Source
ToetsingOnline

Brief title
Focal BMD- changes after instrumented single level lumbar spine fusion

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
- Bone and joint therapeutic procedures

Synonym
single-level posterolateral lumbar spine fusion

Research involving

Human

Sponsors and support

Primary sponsor: Alysis Zorggroep
Source(s) of monetary or material Support: AOspine Europe

Intervention

Keyword: Bone Mineral Density changes, lumbar spine fusion

Outcome measures

Primary outcome

Mean changes in BMD in specific ROI will be evaluated and subsequently be

correlated to one year CT-scan data on

bony fusion.

Secondary outcome

Mean changes in clinical scores (ODI, SF-36, VAS back and leg pain)

radiographic evaluation (X-ray and CT-scan)

Study description

Background summary

Instrumented lumbar spine fusions are performed on a regular basis. Frequently intertransverse bone graft is applied during surgery to facilitate a bony fusion between two spinal segments. In spite of the fact that bony fusion is important for long lasting clinical success, still relatively high non-union rates are reported for spinal fusion procedures. The biological process of bone graft remodelling leading to eventual fusion is still poorly understood and it remains extremely difficult to conclude from regular radiographs whether a true fusion has occurred. There is still demand for a sensitive diagnostic tool to demonstrate a solid spinal fusion and so far CT scan is the best available option to evaluate the actual fusion status of a procedure. CT-scan can not be used on a routine basis to monitor fusion, due to radiation exposure and costs. Therefore it remains important to explore relatively new techniques which may help us to predict whether a spinal fusion occurs or not.

These techniques should not be invasive, have low radiation exposure and should be inexpensive. Modern improvements in DEXA scanning allow us to monitor BMD changes in well defined ROI, with low radiation. This is why DEXA scanning might be an interesting tool to study the process of bone remodelling in the intertransverse fusion area following an instrumented lumbar fusion.

Study objective

The purpose of our study is to evaluate modern dual-energy x-ray absorptiometry scan techniques (iDEXA; General Electronics, USA) as an adjunctive diagnostic tool to evaluate the ongoing process of spinal fusion. Changes in bone mineral density (BMD) will be assessed prospectively, specifically in the intertransverse fusion area. BMD changes in this region of interest may appear to correspond with the process of bone graft remodelling as solid fusion occurs and thus be able to predict succesful bony fusion.

Study design

Prospective cohort study.

Study burden and risks

questionnaires 15 min each visit> 5 times> 1 hour 15 min
DEXA-scan 15 minutens each visit > 4 times > 1 hour

X-rays and CT-scan are usuale care> no extra burden or risk

DEXA-scan has a very low radiation burden (o,ooo5 MsV)> not applicable

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. age 18-80 years
2. low back pain and radicular symptoms caused by lumbar instability
3. leg and/or backpain with one of more of the following phenomena:radiculopathy, sensory deficit, motor weakness, reflex pathology, neurogenic claudication
4. patient has been non-responsive to at least 6 months of non-operative treatment prior to study enrollment
5. fusion of only one lumbar level in the L-3 to S-1 region is indicated

Exclusion criteria

1. indication for multiple levels fusion based on gross instability
2. severe osteoporotic/osteopenic
3. active spinal and/or systemic infection
4. systemic disease or condition, which would affect ability to participate in the study requirements (i.e. active malignancy)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-01-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	24-12-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL28493.091.09