The assessment of bone graft vitality and ingrowth in posterior lumbar fusion (PLIF) using 18F-PET-CT scan.

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The primary objective is to assess the vitality and process of ingrowth of autologous bone graft in PLIF during the first postoperative year in order to predict intervertebral bony union. The second objective is to assess clinical outcome measures.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON39166

Source
ToetsingOnline

Brief title
PLIF using 18F-PET-CT

Condition

- Bone and joint therapeutic procedures

Synonym
lumbar spondylolisthesis, shift vertebrae

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Medtronic Spinal ans Biologics Europe BVBA

Intervention

Keyword: 18-fluoride, PET-CT scan, posterior lumbar interbody fusion (PLIF)

Outcome measures

Primary outcome

(i) Osteoblastic activity (i.e., vitality) and integrity of the bone graft by 18F-PET-CT scan at 6 weeks and 12 months postoperative. (ii) Intercorporal bony fusion by (dynamic) plain radiographs (at 6 weeks and 12 months postop, regular patient care) and a CT-scan (at 12 months postoperative).

Secondary outcome

Improvement in the following clinical outcomes measurements as assessed after 6 weeks and 1 year after surgery in comparison preoperative scores: Oswestry Disability Index, Short form 36 questionnaire, visual analog scale (VAS) and quality of life (EQ-5D).

Study description

Background summary

If conservative measures fail, symptomatic lumbar spondylolisthesis can be treated operatively by posterior lumbar interbody fusion (PLIF) to stabilize the involved vertebral segment. However, in 10 to 20% of cases bony union between the two vertebrae does not occur, which can result in persisting pain and disability. At present, non-union can only be determined reliably by CT-scan no earlier than 1 year postoperatively, when the remodelled bone has been calcified. It would be of great value for clinical practice if non-union could be predicted within a few months after surgery to enable proper therapy adjustment at an early stage.

Study objective

The primary objective is to assess the vitality and process of ingrowth of autologous bone graft in PLIF during the first postoperative year in order to

predict intervertebral bony union. The second objective is to assess clinical outcome measures.

Study design

Prospective pilot study

Study burden and risks

For this pilot study patients will be evaluated by 18F-PET-CT, which is regularly used in standard patient care. Plain radiographs will be taken according to regular patient care at 6 weeks and 12 months postoperatively. At 1 year follow-up a regular CT-scan will be performed as current gold standard assessment of bony union.

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

Age 18-65 years
BMI less than 30 (i.e., non-obese)
Able to speak and write dutch (questionnaires, patient information, informed consent)
Spondylolisthesis L4-L5 or L5-S1, grade I or II
Informed consent agreed
Prepared to adhere to follow-up examinations

Exclusion criteria

Pregnant or trying to conceive
Earlier operative interventions lower lumbar spine
Earlier lumbar spondylodiscitis
Active or recent infection
Active or recent malignancy
Postradiation lumbar region
Inflammatory disease
Deformity
General locomotor disease, e.g. multiple sclerosis, Parkinson disease

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-10-2011
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	01-08-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-04-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL32881.068.11