Feasibility study of cellular titanium cages in lumbar spondylodesis using posterolateral interbody fusion procedure

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The primary objective is to determine the usability of the bony bridging score and to investigate the degree of radiological bone ingrowth in patients who are eligible for a lumbar spinal fusion with PLIF (EIT®) cages.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON46506

Source
ToetsingOnline

Brief title
EIT-3D PLIF Feasibility

Condition

- Joint disorders

Synonym
spondylolisthesis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

Source(s) of monetary or material Support: EIT GmbH

Intervention

Keyword: bone ingrowth, fusion, lumbar spine, spondylodesis

Outcome measures

Primary outcome

The primary outcome is the radiological bone (in)growth one year after the cages are placed and will be determined by the use of a CT-scan. The *bony-bridging score* as developed by SMK radiology will be used.

Secondary outcome

The secondary outcome include the stability of the cages in the intercorporate space. Movement is determined on a lateral X-ray by using the Vertebral Corner Assessment (VCA) based on the Distortion Compensated Rontgen Analysis (DCRA) method. Stability is defined as the absence of micro-movements and migration in the form of subsidence in the underlying adjacent vertebra. Migration is defined as the amount of subsidence of the underlying adjacent vertebral cage (translation (in mm)).

The following parameters are evaluated by using Patient Reported Outcome Measurements (PROMs):

- Function: Oswestry Disabilty Index (v.2.1a)

- Pain intensity: NRS back (0-10) and NRS leg (0-10)

- Quality of Life: MOS-Short Form-36 (SF-36) and EQ5D-3L

- Satisfaction treatment outcome: NRS (0-10)

In addition, the following clinical parameters are evaluated:

- Complications (number and type) in terms of (Serious) Adverse

(Device-related) Events defined prior to the study.

- Re-operations (number) related to the same problem.

Study description

Background summary

A posterior lumbar interbody fusion (PLIF) is an effective surgical technique to reduce symptoms and improve function in patients with spondylolisthesis. The PLIF technique is performed with bilateral interbody cages, like the titanium cages of EIT®. These cages are 3D printed and simulate the bone structure and bone geometry. The cages have a porous architecture similar to the trabecular bone structure. The surface for bone ingrowth is large and could result in bone ingrowth and fusion. It is expected that due to the bone growth into the cage a solid stable bony fusion can be achieved. If it appears that inter corporal fusion with EIT® cages is possible, the use of posterolateral allografts in the PLIF technique will be unnecessary and the risk of subsidence of the cages will be reduced. In literature little is known about valid and reliable measuring and evaluating bone growth. The *bony-bridging-score* is developed to evaluate the anterior lumbar interbody fusion (ALIF) procedure with PEEK cages. It seems that 60% bone ingrowth is possible, however it is unknown whether this outcome measure is also useful for the PLIF procedure with 3D printed Titanium EIT cages.

Study objective

The primary objective is to determine the usability of the bony bridging score and to investigate the degree of radiological bone ingrowth in patients who are eligible for a lumbar spinal fusion with PLIF (EIT®) cages.

Study design

This study has been designed as a single center prospective case series.

Study burden and risks

Patients participating in this study will not be exposed to any barred by any additional risk other than the regular risks for a PLIF procedure. The surgeries will be performed by an experienced orthopaedic surgeon. The

questionnaires and physical examinations will take some extra time, but do not bring any extra burden and are part of routine clinical practice. The additional radiological assessments (1 CT-scan) has a total amount of radiation of 4 mSv per fusion level. Maximal 2 vertebral segments will be included in the study, with a maximum radiation of 8 mSv. This is comparable to the radiation a ski instructor receives during one year of work. A new CT-scanner, the Philips Ingenuity 128, will be purchased in Q3 2018. The CT-scan for this study is planned at the 1 year follow-up assessment. With the new CT-scanner the maximum radiation dose will be reduced to 3 to 4 mSv.

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

Patients with lumbar spondylolisthesis

- Posterior spinal fusion with posterior lumbar interbody fusion (PLIF) procedure (L2-S1), maximal 2 levels
- Aged between 25 and 75 years
- Chronic low back pain with or without leg pain
- Failed conservative treatment at least six months prior to the posterior spinal fusion
- Willingness to participate
- Able to read and speak Dutch

Exclusion criteria

- Previous lumbar fusion at the same level
- Smoking
- BMI >30
- Osteoporosis
- Active, local or systemic infection (rheumatoid arthritis, spondylitis, previous spinal infections, previous spinal trauma)
- Physical, emotional, neurological comorbidities intervening with the compliance monitoring (drug or alcohol abuse, mental illness, general neurological disorders such as Parkinson's, Multiple Sclerosis)
- Oncological or hematological disorders
- Vertebral body fractures
- Pregnancy
- Severe instabilities
- Demonstrated allergy or foreign body sensitivity to the implant material
- Any medical or surgical condition precluding the potential benefit of spinal surgery

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-07-2018

Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	PLIF procedure with 3D printed cages
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-04-2018
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

ID: 20071
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL64253.091.17
OMON	NL-OMON20071