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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20071

Source
NTR

Brief title
3D PLIF feasibility

Health condition

Patients with lumbar spondylosis requiring a posterior spinal fusion with PLIF procedure.

Sponsors and support

Primary sponsor: Sint Maartenskliniek Nijmegen
Source(s) of monetary or material Support: EIT

Intervention

Outcome measures

Primary outcome

Bone ingroth in cages assessed on CT with bony bridging score

Secondary outcome

Functional status, quality of life, pain intenstity in beack and leg, satisfaction

Adverse evants: e.g. complications, re-operation

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 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. However, it is unknown whether this outcome measure is also useful for the PLIF procedure with 3D printed Titanium EIT cages. A single center prospective case series including 15 patients is planned to evaluate the primary objective. The objective is to determine the feasibility and 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 objective

The bony-bridging-score is feasible to use to asses bon ingrowth on a CT-scan at 1 year follow up after postero lateral interbody fusion (PLIF) surgery.

the degree of radiological bone ingrowth in patients who are eligible for a lumbar spinal fusion with PLIF (EIT®) cages.

Study design

preoprative, 3 months and 1 year

Primary outcome is only assessed at1 year follow up.

Intervention

Posterolateral interbody fusion surgery

Contacts

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Eligibility criteria

Inclusion criteria

- Posterior spinal fusion with 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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2018
Enrollment:	15
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 46506
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6700
NTR-old	NTR6870
CCMO	NL64253.091.17
OMON	NL-OMON46506

Study results

Summary results
planned in future