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

Gepubliceerd: 29-11-2017 Laatst bijgewerkt: 15-05-2024

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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20071

Bron
NTR

Verkorte titel
3D PLIF feasibility

Aandoening

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

Ondersteuning

Primaire sponsor: Sint Maartenskliniek Nijmegen
Overige ondersteuning: EIT

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Bone ingroth in cages assessed on CT with bony bridging score

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

preoprative, 3 months and 1 year

Primary outcome is only assessed at1 year follow up.

Onderzoeksproduct en/of interventie

Posterolateral interbody fusion surgery

Contactpersonen

Publiek

Sint Maartenskliniek

Miranda van Hooff
Postbus 9011

Nijmegen 6500 GM
The Netherlands
024 365 9912

Wetenschappelijk

Sint Maartenskliniek

Miranda van Hooff
Postbus 9011

Nijmegen 6500 GM
The Netherlands
024 365 9912

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2018

Aantal proefpersonen:	15
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46506
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
planned in future