Interbody fusion in the treatment of cervicobrachial syndrome; a prospective 5-year follow up extension study of porous titanium cervical cages

Published: 10-06-2021
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Evaluation of longterm clinical and radiological results.

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-OMON50926

Source
ToetsingOnline

Brief title
The EFFECT extension trial

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
- Spinal cord and nerve root disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
cervical herniated disc

Research involving
Human

Sponsors and support

Primary sponsor: neurochirurgie
Source(s) of monetary or material Support: DePuySynthes

Intervention

Keyword: cage, cervical, fusion, titanium

Outcome measures

Primary outcome

The primary outcome measure is improvement in the Neck and Disability Index

(NDI) 5 years after surgery.

Secondary outcome

Secondary outcome measure is the longterm evaluation of bony fusion using

dynamic lateral flexion-extension radiographs that

will be quantitatively analysed. Other outcome measures include improvement in

arm pain and neck pain (VAS), EuroQol-5D and patients' perceived recovery 5

years after surgery.

Study description

Background summary

Based on the previous EFFECT trial, patients treated with 3D printed porous titanium cages have similar fusion rates at 1 year after surgery compared to PEEK although the fusion speed of titanium is faster. Since longterm results of porous titanium is lacking, all patients who participated in the EFFECT trial will be approached 5 years after surgery.

Study objective

Evaluation of longterm clinical and radiological results.

Study design

The EFFECT extension study is designed as a prospective consecutive cohort of the original EFFECT trial with a total follow-up period of 5 years.

Study burden and risks

Patients will be controlled in the outpatient clinic once and have to fill out several questionnaires in addition to one radiograph of the cervical spine.

Contacts

Public
Selecteer

Lijnbaan 32
Den Haag 2512 VA
NL
Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Subject must have completed participation in the EFFECT trial
• Ability and willingness to comply with study requirements

• Written informed consent given by the subject or the subject's legally authorized representati

Exclusion criteria

• Severe mental or psychiatric disorder
• Inadequate Dutch language

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2022
Enrollment:	49
Type:	Actual

Ethics review

Approved WMO

Date:	10-06-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL76079.058.20