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

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**Summary**

**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

No registrations found.

**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

Lijnbaan 32
Den Haag 2512 VA
NL

**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 representative

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
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

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