Long term results of Anterior Lumbar Interbody Fusion (ALIF) with Interbody Fusion Cages.

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What are the long term (follow-up more than 10 years) clinical and radiological results of ALIF with Brantigan ALIF I/F cages?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Observational invasive

Summary

ID

NL-OMON38665

Source
ToetsingOnline

Brief title
ALIF-LT study

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

Synonym
degenerative disc disease, lumbar discopathy

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: afdeling orthopaedie;Medisch Centrum Alkmaar

Intervention

Keyword: ALIF, fusion, intervertebral disc, spine

Outcome measures

Primary outcome

Clinical outcome measures

* Disability

* Quality of Life

* Pain

* Status of return to work and daily activities

Radiographic outcome measures

* Interbody fusion

Other parameters

* Secondary surgical procedures (e.g. revisions or supplemental fixations)

* Complications

Secondary outcome

not applicable

Study description

Background summary

In case of symptomatic degenerative disc disease, spondylolistheses or spondylolysis recalcitrant to non-operative treatment modalities (e.g. physical therapy, bed rest, anti-inflammatory medications), anterior lumbar interbody fusion (ALIF) is considered to be an effective treatment option. Surprisingly,

however, only few studies have been published presenting data on the clinical value of stand-alone ALIF cages. Mid-term results of a cohort of patients surgically treated with an anterior, stand-alone carbon fiber Brantigan ALIF I/F cage between 1993 and 2002 in Medical Centre Alkmaar were already evaluated in 2004. As scientific evidence concerning the long term clinical result of ALIF is lacking, the goal of the current study is to determine the long term clinical outcome and radiographic fusion in this cohort of patients.

Study objective

What are the long term (follow-up more than 10 years) clinical and radiological results of ALIF with Brantigan ALIF I/F cages?

Study design

Observational cross-sectional study

Study burden and risks

Included patients will visit the Medical Centre Alkmaar to undergo additional physical and radiological examination. They will have to fill in a questionnaire, which will take maximally 10 minutes. The time and radiation burden for the subjects are small, and in proportion to the potential value of the research, as no long term results of this surgical procedure are presently known. All patients included in this study will undergo radiographic assessment, which means four radiographs will be performed that the patient otherwise would not have undergone. The mean radiation exposure during one radiograph of the spine is 1,50 mSv (milliSievert). Thus, each patient is exposed to 6,00 mSv. For comparison: yearly background radiation exposure in the Netherlands is around 2 mSv per year.

Contacts

Public
Medisch Centrum Alkmaar

Wilhelminalaan 12 - 038
Alkmaar 1815
NL
Scientific
Medisch Centrum Alkmaar

Wilhelminalaan 12 - 038
Alkmaar 1815

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Participants are patients who already have participated in the study for the mid term assessment

Exclusion criteria

nvt

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	16-11-2013
Enrollment:	51
Type:	Actual

Ethics review

Approved WMO Date:	11-11-2013
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL44767.094.13