# Long-term follow up disc replacements.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON26442

**Source**
NTR

**Brief title**
discus, spine, implants, Long-term FU TDR

**Health condition**

Patients operated for Total Disc Replacement (TDR)due to degenerative disc disease (DDD) in the lumbar spine.

### Sponsors and support

**Primary sponsor:** Prof. dr. L.W. van Rhijn, Head of the department of Orthoepdic surgery, University Medical Center Maastricht, Maastrich, the Netherlands
Contact
E: wil.van.erk@mumc.nl
**Source(s) of monetary or material Support:** n.a.

### Intervention

### Outcome measures

**Primary outcome**

Compare the long term clinical outcome concerning patient’s satisfaction, re-operation rate, disability rate and survival of the TDR to those reported in the literature for spinal fusion.

### Secondary outcome

Significant correlation of IS, AR and/or undersizing AUI with the occurrence of subsidence.

Comparing the clinical outcomes as reported in the questionnaires between patients with- or without subsidence.

The degree of residual mobility and its possible correlation to the occurrence of ASD for which surgery was warranted. Furthermore to compare the ASD rate to those reported literature for spinal fusion

## Study description

### Background summary

Through this study we want to look at the> 20-year survival and clinical follow up of patients who were operated for a disc prosthesis between 1989 and 2000. Primarily we look to the survival of the prosthesis secondary to the clinic and the functioning of patients in daily life.

### Study objective

We hypothesize that implantation asymmetry (IS), angular rotation (AR) and undersizing (AUI) are predictors for the occurring of subsidence. Furthermore we believe subsidence is related to decreased clinical outcomes. Presumably Total Disc Replacement (TDR) facilitates residual motion and leads to less ADR.

### Study design

n.a.

### Intervention

Total Disc Replacement (TDR). TDR aims to reduce pain and restore and maintain motion of the spinal segment, thus reducing the risk of adjacent level degeneration that has been reported for fusion treatment .

# Contacts

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# Eligibility criteria

## Inclusion criteria

o All patients who underwent a TDR using a SB Charité III between 1989 and 2000

## Exclusion criteria

o Deceased without a known TDR revision

# Study design

## Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 02-02-2016 |
| Enrollment: | 150 |
| Type: | Anticipated |

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 02-02-2016 |
| 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

| Register | ID |
|---|---|
| NTR-new | NL4468 |
| NTR-old | NTR5710 |
| Other | 16-N-22 : 16-N-22 |

## Study results

**Summary results**

n.a.