Wear analysis of cross-linked versus conventional polyethylene acetabulum cups in cemented primary total hip arthroplasty

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22863

Source
NTR

Brief title
FAL cup trial

Health condition

Total hip arthroplasty
Wear
Cross-linked
Polyethylene

Sponsors and support

Primary sponsor: Department of Orthopedic surgey, Medical Centre Leeuwarden
Source(s) of monetary or material Support: Department of Orthopedic surgery, Medical Centre Leeuwarden.
Link Nederland B.V., Schiedam

Intervention

Outcome measures

Primary outcome

Mean annual polyethylene wear rate in millimetres at 5 years postoperatively

Secondary outcome

1. Mean annual polyethylene wear rate in millimetres at 1, 3 and 10 years postoperatively

2. Mean scores on patient reported outcomes measures (NRS pain, HOOS-PS, OHS, EQ-5D and SQUASH) at 1, 3, 5 and 10 years postoperatively

3. Number of peri-prosthetic lucencies in the 3 zones according DeLee and Charnley at 5 and 10 years postoperatively

4. Number of revisions at 5 and 10 years postoperatively

5. Mean total intramural costs at 5 and 10 years postoperatively

Study description

Study objective

It is hypothesized that at 5 year postoperatively, mean annual wear rate in millimetres of the cross-linked polyethylene FAL cups is significantly less compared to the conventional polyethylene FAL cups.

Study design

Preoperatively and postoperativey at 6 weeks, 3 months, 1 year, 3 years, 5 years and 10 years

Intervention

Patients will receive a crosslinked polyethylene FAL cup® (Link) or a conventional polyethylene FAL cup. The femoral stem will be the SP II® (Link). All surgeons will peform a posterolateral surgical approach. All patients will be treated postoperatively following a standardized protocol.

Contacts

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Eligibility criteria

Inclusion criteria

Patients with

1. age 65- 80 years

2. symptomatic coxartrosis and scheduled for a cemented total hip replacement

3. physical and mentall ability to come for the postoperative follow-up visits

4. written informed consent

Exclusion criteria

Patients with:

1. standard contraindications for total hip replacement, such as infection and severe pulmonary, cardiovascular or metabolic comorbidity

2. neurlogical disorders that affect walking

3. an inability to fill in the questionnaires due to mental or cognitive impairments

4. insufficient understanding of the Dutch language

5. a Body Mass Index > 40

6. an abnormal hip joint anatomy not suitable for the use of the FAL cup and SPII stem

7. an amputation of the lower extremity

8. malignancy receiving anticancer therapy

9. participation in another trial that might interfere with this study

10. an alcolhol or drug dependency

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-04-2015
Enrollment:	106
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-06-2017

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40132
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6597
NTR-old	NTR6814
CCMO	NL46774.099.13
OMON	NL-OMON40132

Study results