Wear analysis of cross-linked versus standard polyethylene F.A.L. acetabular cups in patiënts with symptomatic coxarthrosis: a randomized controlled trial

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Primary goal: mean linear wear of the cross-linked polyethylene F.A.L. cup compared to the mean linear wear of the standard polyethylene F.A.L. cup at 5 years postoperatively. Secondary goals:1. mean linear wear (millimeters/year) at 1 year, 3 years...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON40132

Source
ToetsingOnline

Brief title
F.A.L. cup trial

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
symptomatic coxarthrosis - wear of the hip joint

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Firma Link Nederland te Schiedam

Intervention

Keyword: acetabular cups, polyethylene, total hip arthroplasty, wear analysis

Outcome measures

Primary outcome

Mean linear wear of the cross-linked polyethylene F.A.L. cup compared to the

mean linear wear of the standard polyethylene F.A.L. cup at 5 years

postoperatively.

Secondary outcome

1. mean linear wear (millimeters/year) at 1 year, 3 years and 10 years

postoperatively

2. patient reported outcome measures (HOOS-PS, Oxford Hip Score, pain score,

EQ5D and the SQUASH) at 1 year, 3 years 5 years and 10 years postoperatively

3. number of periprosthetic radiolucencies at 5 years and 10 years

postoperatively

4. survival of the implant at 5 years and 10 years postoperatively

5. total inpatient costs 10 years postoperatively

Study description

Background summary

Aseptic loosening is the most common reason for the failure of a total hip replacement and subsequent revision surgery. Histological and in vitro studies have shown that polyethylene wear particles can play an important role in the

loosening process of the implant. A higher wear resistance of polyethylene can be achieved by cross-linking, that is obtained when the polyethylene is irradiated with gamma rays. Wear simulation studies and clinical studies have shown that the wear of cross-linked polyethylene acetabular cups significantly decreases compared to standard polethylene.
The F.A.L. ® acetabular cup (Link, Hamburg, Germany) is, in addition to the standard polyethylene cup, also available in a cross-linked polyethylene version. Because producers of cross-linked polyethylene maintain own production methods with different radiation protocols, there is no standardized 'standard ' or 'cross-linked' polyethylene and are the results of the various cups not interchangeable or generalizable.
The F.A..L. cup with standard polyethylene has good wear results and an excellent survival rate. The question is whether this can be improved by the cross-linked variant.
The hypothesis of this study is that the mean linear wear rate of the cross-linked polyethylene F.A.L. cup is significantly less than the mean linear wear of the standard polyethylene F.A.L. cup in the general patient population with symptomatic coxarthrosis and an indication for a cemented hip replacement.

Study objective

Primary goal: mean linear wear of the cross-linked polyethylene F.A.L. cup compared to the mean linear wear of the standard polyethylene F.A.L. cup at 5 years postoperatively.

Secondary goals:
1. mean linear wear (millimeters/year) at 1 year, 3 years and 10 years postoperatively
2. patient reported outcome measures (HOOS-PS, Oxford Hip Score, pain score, EQ5D and the SQUASH) at 1 year, 3 years 5 years and 10 years postoperatively
3. number of periprosthetic radiolucencies at 5 years and 10 years postoperatively
4. survival of the implant at 5 years and 10 years postoperatively
5. total inpatient costs 10 years postoperatively

Study design

A prospective, randomized clinical trial comparing two types of polyethylene (crosslinked versus standard) acetabular cups with similar design.

Intervention

Patients will receive a cemented total hip arthroplasty: F.A.L. cup and SPII stem

Group 1: crosslinked polyethylene F.A.L. cup and SPII stem
Group 2: standard polyethylene F.A.L. cup and SPII stem

Study burden and risks

The visits, including making standard x-rays and filling in questionnaires,at 6 weeks, 3 months, 1 year, 5 years and 10 years postoperatively are part of usual care, with the exception of the SQUASH.
The consultation (interview and physical examination) at the orthopaedic surgeon and the x-rays will take about 20 minutes. Filling in the questionnaires costs about 15 minutes.
The visit preoperatively to the researcher and postoperatively to the orthopepaedic at 3 years are extra for the F.A.L. cup trial.
Since the F.A.L. cup is already applied extensively, there are for this study no additional risks expected other than the general risks as associated with a cemented total hip replacement.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Age 65 - 80 years
2. Symptomatic coxarthrosis and an indication for a cemented total hip prothesis
3. Physically and mentally able to attend the postoperative follow-up evaluations
4. Signed informed consent form

Exclusion criteria

1. Standard contraindications to elective (un)cemented total hip athroplasties
2. Neurological disorders that affect walking
3. Physical or mental disabilities that could affect judgment or filling out the questionnaires
4. Not literate in Dutch
5. Body Mass Index > 40
6. An abnormal hip anatomy because of which the F.A.L. cup and SPII stem cannot be placed
7. Amputation of het lower extremity
8. Malignancies and currently receiving cytostatic therapy
9. Participation in another study that conflicts with the F.A.L.cup trial
10. Addiction to drugs or alcohol
11. Cup inclination of > 55 degrees

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-07-2015
Enrollment:	106
Type:	Actual

Medical products/devices used

Generic name:	Flanged Anti-Luxation (F.A.L.) acetabulum cup
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-04-2015
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	12-07-2018
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22863
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL46774.099.13
OMON	NL-OMON22863