Randomized controlled study comparing the Taperloc complete versus the Taperloc complete Microplasty.

Published: 23-12-2016
Last updated: 19-04-2024

Objective: Evaluate the safety and effectiveness of two cementless Taperloc versions (Taperloc complete versus Taperloc complete Microplasty)

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

Summary

ID

NL-OMON46938

Source
ToetsingOnline

Brief title
Taperloc Microplasty

Condition

- Joint disorders

Synonym
hip artrosis, hip wear

Research involving
Human

Sponsors and support

Primary sponsor: Zimmer Biomet Nederland BV
Source(s) of monetary or material Support: Zimmer Biomet

Intervention

Keyword: Osteoarthritis, RSA, Short stem, Uncemented hip arthroplasty

Outcome measures

Primary outcome

Primary study endpoint is migration at two year measured with RSA

Secondary outcome

Secondary study parameters/endpoints are malalignment, incorrect sizing,

subsidence and intraoperative fractures, early survival of the hip prosthesis

at 2 year and Clinical performance based on the clinician based outcome (HHS

and radiological evaluation) and the patient based outcomes (HOOS, EQ5D, Oxford

Hip score, Forgotten Hip).

One site will perform migration analysis with RSA. Migration at two year will

be the primary endpoint for this sub-group.

Study description

Background summary

The Taperloc Microplasty stem and the Taperloc Complete Distal Reduced stem are already used in the clinic for a while, but are not tested enough in direct comparison studies. Besides these stems, a variation of the cup is used which ability to establish bone ingrowth has not been investigated directly in a clinical trial. This randomized clinical trial with RSA investigated the outcomes of the surgery and the short term outcomes (until 2 years post-operatively).

Study objective

Objective: Evaluate the safety and effectiveness of two cementless Taperloc versions (Taperloc complete versus Taperloc complete Microplasty)

Study design

Prospective two Arm Randomized Controlledmulti-center Trial. All included patients will be assessed preoperative and directly postoperative. Follow-up will take place at 6 weeks or 3 months (TBD), 1 and 2 years postoperatively. Assuming the enrolment will be completed in one year total study duration will be 3 years.

Intervention

Two different hip prostheses with CE mark with known mid to long term follow up clinical will be used. All patients will receive a total hip prosthesis because of their invalidity and health problems which will be followed by clinical and radiological evaluation.

Study burden and risks

Subjects participating in the study have the same risks and benefits when not participating in the study. The Taperloc is clinically successfully used for thirty years. The Taperloc Complete has a ODEP 10A rating (Highest rating available) and the Taperloc Complete Microplasty has a 5A rating. Follow-up visits are the same as standard practice in the participating hospitals.

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

These are standard indications for usage of the Taperloc Complete and Taperloc Microplasty stem. ;Subjects with one of the following indications:
Non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis and rheumatoid arthritis.
Correction of functional deformity. ;Additional inclusion criteria include:
Male or female
> 18 and * 70 years of age
Subjects willing to return for follow-up evaluations.
Subjects able to read and understand Dutch language.

Exclusion criteria

Active Infection (or within 6 weeks after infection)
Sepsis
Osteomyelitis;Uncooperative patient or patient with neurologic disorders who are incapable of following directions
diagnosed Osteoporosis or Osteomalacia
Metabolic disorders which may impair bone formation
Distant foci of infections which may spread to the implant site
Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram
Vascular insufficiency, muscular atrophy or neuromuscular disease.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-06-2017
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Total hip prosthesis
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	23-12-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	12-12-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	14-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

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	NL54031.098.15