A Cement Compression Device for cemented TKA

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

Summary

ID

NL-OMON49376

Source
ToetsingOnline

Brief title
CDCS

Condition

- Joint disorders

Synonym
Knee osteoarthritis, knee wear

Research involving
Human

Sponsors and support

Primary sponsor: Reinier Haga Orthopedisch Centrum
Source(s) of monetary or material Support: vakgroep Orthopedie RdG

Intervention

Keyword: Cement compression device, Cemented TKA

Outcome measures

Primary outcome

The main study parameters are the penetration and distribution of the cement

into the bone of the proximal tibia, measured with CT.

Secondary outcome

The secondary parameter is the measured operation time.

Study description

Background summary

Aseptic loosening is a common problem in joint arthroplasty and one of the most common indications for revision arthroplasty in total knee arthroplasty (TKA).

Aseptic loosening occurs mostly at the tibia component and might be caused by suboptimal fixation of the prosthesis. Knee prostheses fixated with bone cement (Polymethylmethacrylaat = PMMA) have equally good or even better results regarding aseptic loosening and clinical outcome than knee prostheses fixated without bone cement. The key to optimize the interfacial strength is achieving and maintaining maximal infiltration of cement into the bone to obtain large inter-digitation and a large contact area. To improve the cement penetration a compression device was designed. This device prevents cement leakage and improves the cement penetration and distribution into the proximal tibia in a cadaver model.

It is hypothesized that cementation in the proximal tibia after a TKA with the new cementing compression device is better compared to the best cementing technique at the moment (finger packing) regarding cement distribution and cement penetration in vivo.

Study objective

The primary objective is to compare cementation during TKA with a new cementing device to finger packing (the current best cementing technique) regarding cement distribution and cement penetration of the proximal tibia.

The secondary objective is to compare the operation time for TKA with and without this new cementing device.

Study design

We will perform a prospective randomized controlled trial at the Reinier de Graaf Hospital, Delft, The Netherlands. Patients will be recruited from the outpatient clinic of the orthopaedic department and evaluated preoperatively, operatively, 6 weeks and 3 months after surgery.

Intervention

use of the cement compression device during cementation of a total knee arthroplasty

Study burden and risks

Subjects participating in this stuy have the same risks and benefits when not participating in this study. We will compare a well recommended technique (finger packing) with a new technique using a device that is already tested in a cadaver study. The benefit should be that the penetration and distribution of the cement in the group using the cementing compression device is more uniform and predictable. To evaluate the cement distirbution and penetration, a CT scan of the knee is necessary, 3 months after surgery. This CT scan is extra compared to regular care.

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

- Non-inflammatory degenerative joint disease (NIDJD), e.g. osteoarthritis, avascular necrosis
- Traumatic arthritis
- The need for a tibia component size 4, 5, or 6 (NexGen Legacy, Zimmerbiomet) during surgery

Patients must additionally meet all of the following criteria:
- Age > 18 years
- Patient is willing to participate
- Patient is able to speak and write Dutch
- Patient qualifies for TKP based on medical history and physical examination
- Patient is able and willing to provide written informed consent

Exclusion criteria

- Rheumatoid arthritis or other forms of inflammatory disease
- Uncooperative patient or patient with neurologic disorders who are incapable of following directions
- Insufficient bone stock to provide adequate support and/or fixation to the prosthesis
- Metabolic disorders which may impair bone formation
- Osteomalacia
- Charcot's disease
- Previous knee surgery except arthroscopy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-01-2020
Enrollment:	34
Type:	Actual

Medical products/devices used

Generic name:	Cement compression device
Registration:	No

Ethics review

Approved WMO

Date:	22-10-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	17-08-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	28-08-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	08-11-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	07-03-2021
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	NL70830.098.19