Validation and implementation of the Comforthod-Knee System for accurate diagnosis of mechanical loosening and movement of a metal implant in the human body.

Published: 07-04-2015
Last updated: 19-08-2024

The goal of this study is to measure the amount of movement of the knee prosthesis in relation to the bone with the use of the Comforthod system. So an objective discrimination can be made whether a prosthesis is loose or fixed.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON52996

Source
ToetsingOnline

Brief title
Diagnosis of mechanical loosening using the Comforthod Knee System.

Condition

- Other condition
- Joint disorders

Synonym
aseptic loosening, mechanical loosening

Health condition

Knie prothese

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: NWO

Intervention

Keyword: Comforthod Knee, Mechanical Loosening, TKA

Outcome measures

Primary outcome

The primary outcome measure of this study is the amount of movement of the prosthesis relative to adjacent bone. The amount of movement is expressed in movement in the screw axis, rotation of the prosthesis and movement in the x, y and z plane.

These outcomes will be compared with the findings of the standard care pathway and the findings during revision surgery.

The amount of movement of the prosthesis relative to the adjacent bone as measured in asymptomatic patients will be compared to amount of movement found by Comforthod system in patients were the TKA was found to be loose intra-operatively.

Secondary outcome

Secondary outcome measure is the difference between the two groups in the amount of prosthesis movement with the
adjacent bone. The amount of movement is expressed in movement in the screw

axis, rotation of the prosthesis and

movement in the x,y and z axis.

Study description

Background summary

Total Knee Arthroplasty (TKA) is a highly effective treatment for pain and loss of function caused by rheumatoid arthritis or osteoarthritis of the knee. The utilization of TKA has increased significantly over the last years. Although TKA is a very successful surgical procedure showing satisfactory results, failure does occur and results in persistent knee pain. The main cause for revision after TKA is aseptical loosening. The technique to diagnose TKA loosening remain unspecific. It is a combination of tests that can only detect secondary effects of prosthesis loosening and the clinical suspicion that can be made by physical examination. Altogether the diagnostic process can last six months and most often ends in a diagnosis of loosening with only 70-75% sensitivity and specificity.

Study objective

The goal of this study is to measure the amount of movement of the knee prosthesis in relation to the bone with the use of the Comforthod system. So an objective discrimination can be made whether a prosthesis is loose or fixed.

Study design

This clinical diagnosing study evaluates the use of Comforthod system compared to the gold-standard diagnostic tool for loosening of the prosthesis.
This study will take place with patients that are scheduled for revision surgery because of clinical suspicion for aseptic loosening.

Study burden and risks

All patients in this study will undergo an extra examination. The examination consist of the use of the Comforthod system in combination with a CT-scan in which a radiation doses of 1.2 mSv will be inflicted to the lower limb. The maximum force that the Comforthod system inflicts to the lower limb is 20 Nm. The 20 Nm is less than the daily forces a leg with a knee prosthesis will endure. With this knowledge the expectation is that the use of the Comforthod system will not bring an extra burden or risk to the patient.

The benefit for this study population is that this will be the first time that

a direct diagnosing tool will be used to determine whether a knee prosthesis is fixed or loose. The outcomes of this study could possibly contribute to reduced length and lower costs of the diagnosing process for aseptical loosening of a TKA.

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

-Patients diagnosed with aseptic loosening of the knee prosthesis and that are scheduled for revision surgery.
- Patients with a TKA who are asymptomatic and have no complaints oftheir knee prosthesis.
- Patients capable of giving informed consent and are willing to do this extra

examination

Exclusion criteria

- Patients with another cause for revison surgery besides aseptic loosening.
- Patients who are unable or unwilling to sign the informed consent for this study.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2015
Enrollment:	74
Type:	Actual

Ethics review

Approved WMO Date:	07-04-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	22-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-07-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL49757.018.14