Adequately Diagnosing Total Knee Arthroplasty Loosening: a Randomized Controlled Trial Evaluating the AtMoves Knee System in a Routine Clinical Setting

Published: 05-12-2024
Last updated: 18-01-2025

The primary objective of this study is to evaluate the efficacy of the AtMoves Knee System in the clinical diagnostic process of aseptic knee loosening in knee prostheses. This will be measured by the number of *failed outcomes* resulting from…

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

Summary

ID

NL-OMON57182

Source
ToetsingOnline

Brief title
DIGITAL-KNEE

Condition

- Joint disorders

Synonym
looseness, Loosening

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC

Source(s) of monetary or material Support: NWO;TKI-PPP grant

Intervention

Keyword: Aseptic, Diagnostic, Loosening, Total Knee Arthroplasty

Outcome measures

Primary outcome

The primary outcome measure is the status of the surgical procedure as a *failed outcome* as determined according to the delta KOOS-PS score < MCID.

Secondary outcome

Secondary study parameters are: (1) the number of participants between the two arms that undergo revision surgery in the 12 months follow up period despite the initial decision (based on the diagnostic pathway) to not perform revision surgery, (2) the number and types of diagnostic measures used between the two groups, along with the potential cost reduction by avoiding unnecessary revision surgery, and (3) societal productivity loss and medical consumption after the final diagnosis and treatment decision and, (4) subject and physician satisfaction with the diagnostic process between the two groups.

Study description

Background summary

Rationale:
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 use of TKA has increased dramatically in recent years. Although TKA is a very successful surgical procedure with satisfactory results, failure occurs and results in persistent knee pain, reducing function. The main cause for revision of a TKA is aseptic loosening, mainly of the tibial component. Current diagnostic procedures are not completely adequate to determine TKA loosening.

This results in approximately 25-30% unnecessary revision surgeries, where at the time of surgery the TKA is found not to be loose.

The AtMoves Knee System is a new technique developed to diagnose TKA release by measuring the motion between the prosthetic component and adjacent bone as caused by external loading of the knee. The measurement is performed on CT scans of the loaded knee with a TKA. Using the AtMoves Knee System hardware component, the loading device, the knee with the TKA is loaded with a bending moment in the frontal plane, first in varus and second in valgus. With each load, a CT scan of the bones and prosthetic components is taken. Using the AtMoves Knee System software, the relative motion of the prosthetic component to the bone is reconstructed and calculated from the three-dimensional CT scan data.

AtMoves Knee System is expected to be a cheaper alternative to currently used nuclear imaging techniques, such as bone scintigraphy and PET-CT scan. This nuclear imaging only reveals biological activity in the bone surrounding the prosthetic components. Therefore, nuclear imaging provides only indirect evidence of prosthetic loosening and the outcome is often inconclusive, unlike AtMoves Knee System, which provides actual data on the degree of TKA loosening.

The primary hypothesis is that the number of *failed outcomes* is lower after using AtMoves Knee System in the diagnostic process, as opposed to using standard imaging in the diagnostic process.

Study objective

The primary objective of this study is to evaluate the efficacy of the AtMoves Knee System in the clinical diagnostic process of aseptic knee loosening in knee prostheses. This will be measured by the number of *failed outcomes* resulting from incorrect diagnosis.

Study design

The study is a prospective, randomized, controlled, national diagnostic multicenter trial.

Intervention

The subject in the intervention group receives the AtMoves Knee System evaluation, which includes both diagnostic reprocessing according to the standard protocol along with two CT scans of the affected knee with opposing varus and valgus loads as applied by the AtMoves Knee System loading device. The AtMoves Knee System software calculates the relative motion between the knee prosthetic component and the surrounding bone.

Study burden and risks

According to the initial routine reprocessing, the medical history is taken, the physical examination is performed and a series of X-rays are taken regularly. Only if the attending surgeons feel that an additional examination is necessary, the subject is randomized into the intervention group or control group. In the intervention group, the subject undergoes AtMoves Knee System examination, i.e., CT imaging of the loaded knee.

The AtMoves Knee System examination consists of loading the knee and a simultaneous CT scan of the knee and lower leg. The loads applied to the knee by the AtMoves Knee System loading device are two bending moments in the frontal plane of up to 20 Nm, in the varus and valgus directions. A CT scan is taken at each loading. The loading of 20 Nm is less than the varus and valgus load on the knee with a knee prosthesis during normal daily activities. The total radiation does

Contacts

Public
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

To be eligible to participate in this study, subjects must meet all of the following criteria:
- Subjects must have undergone unilateral or bilateral total knee arthroplasty.
- Total knee arthroplasty surgery must have been performed at least one year ago.
- Subjects must be suspected of aseptic loosening of the knee prosthesis.
- The treating orthopedist must deem additional examination (other than standard diagnostics) necessary to reach a sound diagnosis.
- Subjects must be able to give informed consent and be willing to undergo research using the AtMoves Knee System.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Subjects with another cause for revision surgery other than aseptic loosening (e.g. septic loosening)
- Subjects with surgical interventions of the index knee in the year prior to the start of the complaints associated with TKA loosening.
- Subjects with presence of systemic musculoskeletal diseases.
- Subjects with a non-consolidated peri-prosthetic fracture of the bone around the TKA.
- Subjects with pregnancy or suspected pregnancy.
- Subject who are unable or unwilling to sign the informed consent for this study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2024
Enrollment:	124
Type:	Anticipated

Medical products/devices used

Generic name:	AtMoves Knee System
Registration:	No

Ethics review

Approved WMO

Date:	05-12-2024
Application type:	First submission
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	NL82293.018.24