# Preservation of both cruciate ligaments as essential step to the forgotten knee. Do we need the anterior cruciate ligament for better functional outcomes? A randomized controlled gait analysis trial

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Primary Objective:To evaluate tibia rotation after TKA with the Vanguard total knee system with either the XP tibia implant compared to thestandard CR tibia implant.Secondary Objective:Comparing operative, clinical and radiological outcome of either...

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| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Joint disorders |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON48002

**Source**
ToetsingOnline

**Brief title**
Rotation stability after preservation of the ACL in TKA

### Condition

- Joint disorders

**Synonym**
Anterior Cruciate Ligament, movement analysis

**Research involving**

Human

## Sponsors and support

**Primary sponsor:** Zuyderland Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** anterior cruciate ligament, Gait analysis, tibial rotation, TKA

## Outcome measures

### Primary outcome

Rotational degrees of freedom of the tibial implant, measured with 3-D motion

analysis after operation and compared

between the XP tibia implant and CR conventional tibia implant

### Secondary outcome

Comparing operative, clinical and radiological outcome of either the XP tibia

implant compared to the

standard CR tibia implant.

standard intramedullary alignment guides.

# Study description

### Background summary

The aim of the present prospective randomized clinical trial was to evaluate and compare the rotational laxity and stiffness
after TKA with or without preservation of the ACL using 3-D motion analysis for evaluation of rotational biomechanics. We
hypothesized that preservation of the ACL would result in better rotational stability than TKA without ACL

### Study objective

Primary Objective:
To evaluate tibia rotation after TKA with the Vanguard total knee system with either the XP tibia implant compared to the
standard CR tibia implant.

Secondary Objective:
Comparing operative, clinical and radiological outcome of either the XP tibia implant compared to the
standard CR tibia implant.

### Study design

A prospective, randomized, double blind controlled study.

### Study burden and risks

Besides the usual visits to the clinic, we ask the patient to travel four times to Heerlen for gait analysis. All in all, this
study will last about an hour. The movement analysis uses infrared cameras that only measures reflective beads (skin
markers) attached on the skin. In addition, the muscle activity is measured with the aid of an EMG (Electromyogram). This
is a wireless EMG that are NOT using needles and is absolutely pain free.

The risks associated with this research will be nil. Some physically demanding tests are performed during the analysis. It
may be that this irritation of the knee and has muscle aches as a result. In the worst case there is a chance tearing the ACL
during the movement tasks. However, the likelihood of this is very small, because the movements are carried out in a very
controlled situation and which also occur in the daily life.

## 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

•Indicated for a TKA
•Patients with pre-existing contra lateral knee surgery
•Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, or traumatic arthritis where one
or more compartments are involved
•Correction of varus, valgus, or posttraumatic deformity
•Sufficient soft tissue surrounding the knee, including the ACL and PCL
•High need to obtain pain relief and improve function
•Body-mass-index (BMI) <35
•Ability and willingness to follow instructions, including control of weight and activity level, and to return for followup
evaluations.
•Consent form read, understood and signed by patient.

## Exclusion criteria

•BMI =>35
•Use of Anterior Stabilized Bearings or Posterior Stabilized Bearings
•Patients with severe pre-operative varus or valgus deformity =>15 degrees
•Correction or revision of previous joint replacement procedure on index knee
•Sepsis
•Osteomyelitis
•Active infection in knee
•General infection

•Distant foci of infections which may spread to the implant site
•Failure of previous joint replacement
•Pregnancy
•Previous major knee surgery, except for arthroscopic meniscectomy.
•Metal near knee joint (MRI-scan not possible)
•Rheumatoid arthritis
•Extension deficit >15 degrees
•Flexion <100 degrees.
•Non-correctable varus axis
•Cruciate ligament insufficiency
•Rapid joint destruction, marked bone loss, or bone resorption apparent on roentgenogram
•Uncooperative patient or patient with neurological disorders who is incapable of following directions
• Osteoporosis, metabolic disorders and osteomalacia on the basis of the X-ray which is evaluated by the
orthopedic surgeon

# Study design

## Design

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|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Completed |
| Start date (anticipated): | 25-08-2020 |
| Enrollment: | 64 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 10-02-2020 |
| Application type: | First submission |
| Review commission: | METC Z: Zuyderland-Zuyd (Heerlen) |

# 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 | NL72272.096.19 |