# Onderzoek naar de draaistabiliteit van de knie na reconstructie van de voorste kruisband.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON27173

**Source**
Nationaal Trial Register

**Health condition**

Het doel van het onderzoek is om een beter beeld te krijgen van de stabiliteit van knieën met een intacte kruisband, een afgescheurde kruisband, een anatomisch en transtibiaal gereconstrueerde kruisband.

The aim of the research is to better understand the stability of knees with an intact ACL, an defecit ligament, an anatomical and transtibial reconstructed ACL ligament.

### Sponsors and support

**Primary sponsor:** dr EJP Jansen (MD, PhD)
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**Source(s) of monetary or material Support:** None to be reported

### Intervention

## Outcome measures

### Primary outcome

Our first outcome of interest will be the tibial rotation excursion. This is the graph which we can draw from our gait analysis system which measures the position of the tibia in relation to that of the femur and allows us to see the angle of rotation.

### Secondary outcome

Additionally, we keep track of our patients' well-being and satisfaction using several questionnaires. We will use questionnaires and clinical tests that have been recommended by the Nederlandse Orthopaedische Vereniging (NOV):

1. Knee Injury and Osteoarthritis Outcome score (KOOS) (Questionnaire);

2. International Knee Documentation Committee (IKDC) (Questionnaire);

3. Tegner sports activity score
(Questionnaire);

4. Lachman Test
(Clinical Test);

5. Anterior Drawer Test
(Clinical Test);

6. Pivot Shift Test
(Clinical Test).

We will also take several other values into account that the VICON system generates automatically when we perform our 3D gait analysis:

1. Dynamic EMG Measurement;

2. Knee moments;

3. Foot approach angle.

# Study description

### Background summary

Experiments dealing with the rotational stability after an ACL reconstruction have not been

performed in vivo or were performed under static conditions. Although static rotational stability testing is currently the standard, many studies have shown that static stability tests are often incapable of correlating with functional outcome following anterior cruciate ligament-reconstruction-surgery. Through in vivo testing in dynamic weight bearing knees we expect to get a better view of the actual rotational pivoting forces in the knee.

Participants will be recruted by Dr P Deckers (MD) from the Dep. of Orthopedic surgery Atrium MC in Heerlen, Dr P Emans (MD, PhD) from the Dep. of Orthopedic surgery AZM in Maatricht and Dr EJP Jansen (MD, PhD) from the Dep. of Orthopedic surgery Orbis MC in Sittard-Geleen.

**Study objective**

Theoretically the anatomical reconstruction technique might give better results in rotational stability due to a more anatomical placement of the ACL-graft. Though it is difficult to test this correlating to functional outcome, because in current literature there seems to be no significant difference between both surgical techniques. Moreover, statically performed anterolateral rotational instability tests do not reproduce the forces loaded onto an in vivo anterior cruciate ligament. Through in vivo kinematic 3D- gait analysis, we aim to measure statistically and clinically significant differences in tibial rotational excursion when patients perform several motor tasks.

**Study design**

On the Gait-lab test day participants will be required to come to the Maastricht University Movement Laboratory. On this day they will follow the regimen described below.

Test day Schedule:

1. Physical examination (5-10 minutes);

2. EMG placement and maximum force determination (10-15 minutes);

3. Skin marker placement (5-10 minutes);

4. Skin marker calibration (5-10 minutes);

5. Vicon Gait analysis (10 minutes);

6. Questionaires (10-20 minutes).

Total time 35-55 (47-75) minutes

**Intervention**

The transtibial ACL reconstruction. In this technique the orientation of the femoral tunnel depends on the orientation of the tibial tunnel, because the femoral tunnel is created through the tibial tunnel. In this way a non-anatomical reconstruction is performed.

The anatomical ACL reconstruction aims to better restore this rotational stability by placing an extra anteromedial arthroscopy portal through which the femoral tunnel can be reamed more laterally and more diagonally oriented, hereby placing the graft in a more anatomical orientation similar to the native ACL.

# Contacts

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# Eligibility criteria

## Inclusion criteria

Universal Inclusion criteria:

1. Age 18-40 years;

2. Able to understand and speak the Dutch or English language.

Healthy Control group:

1. No history of knee ligament or meniscal injury.

ACL Deficient Group:

1. Diagnosed ACL rupture with MRI or surgical knee arthroscopy;

2. Primary ACL rupture.

Transtibial Reconstruction group:

1. Received transtibial ACL reconstruction minimally one year ago.

Anatomical Reconstruction group:

1. Received anatomical ACL reconstruction minimally one year ago.

## Exclusion criteria

Universal Exclusion criteria:

1. Not able and willing to sign informed consent;

2. BMI > 30.

ACL Deficient Group:

1. Ligament injury to the contralateral knee.

Transtibial Reconstruction group:

1. Ligament injury to the contralateral knee.

Anatomical Reconstruction group:

1. Ligament injury to the contralateral knee.

# Study design

## Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 02-04-2013 |
| Enrollment: | 80 |
| Type: | Anticipated |

## IPD sharing statement

**Plan to share IPD:** Undecided

# Ethics review

Positive opinion

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|---|---|
| Date: | 14-03-2013 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 39154
Bron: ToetsingOnline
Titel:

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL3729 |
| NTR-old | NTR3892 |
| CCMO | NL40420.068.12 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |
| OMON | NL-OMON39154 |

# Study results

**Summary results**
N/A