# (R)esearch in (A)cute vs (D)elayed (A)CL (R)econstruction

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To investigate the (cost) effectiveness of early ACL reconstruction (3 months after injury). Hypotheis is that early ACL reconstruction results in less loss of function and muscle strength of the knee and in an faster return to the pre-injury level...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

# Summary

### ID

NL-OMON39825

**Source** ToetsingOnline

**Brief title** RADAR

## Condition

• Tendon, ligament and cartilage disorders

#### Synonym

Anterior Cruciate Ligament instability, giving way

#### **Research involving** Human

### **Sponsors and support**

Primary sponsor: Academisch Medisch Centrum Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW

### Intervention

Keyword: ACL, ACL reconstruction, outcome, timing of surgery

### **Outcome measures**

#### **Primary outcome**

Hypothesis: An early ACL-reconstruction will give a shorter period of time-off sports. This will be measured with objective measurements, like various hop tests and proprioception and coordination tests. To investigate whether an early ACL-reconstruction results in a faster functional recovery and a higher level of physical functioning, compared to the usual timing (>3 months after ACL rupture)

#### Secondary outcome

Secondary study parameters: The costs associated with the ACL reconstruction

and rehabilitation and costs associated ( time off work, fysiotherapeutic

costs, etc) are investigated. The expectation is that they will be lower.

# **Study description**

#### **Background summary**

An anterior cruciate ligament (ACL) rupture is a common injury of the knee in sports with many pivoting movements such as football, handball, volleyball and basketball. In case of instability of the knee and the desire of the patient to return to his / her pre-injury level of sports, a surgical reconstruction of the ACL is recommended. Current guidelines recommend first 3 months of physiotherapy before an ACL reconstruction is performed. However, because of improvements in arthroscopy and physiotherapy, it is possible to perform an ACL reconstruction within the first weeks following the injury. Potential added value of early ACL reconstruction may be that a patient has less loss of function of the knee and may also return earlier to his / her pre-injury level of activity. Secondary, it is expected that early ACL reconstruction will result in a significant cost reduction because physical therapy prior to ACL

reconstruction is shortened and it is expected that the postoperative treatment process also will be shorter. The little scientific research that has been done on this subject, confirm that an earlier timing of ACL reconstruction results in comparable or better outcome, compared to the ususal timing. However, the evidence is scarce and no RCT has been conducted on this subject.

### **Study objective**

To investigate the (cost) effectiveness of early ACL reconstruction (<6 weeks after injury), compared to the usual timing of ACL reconstruction (> 3 months after injury). Hypotheis is that early ACL reconstruction results in less loss of function and muscle strength of the knee and in an faster return to the pre-injury level of activity.

### Study design

A prospective randomized multicenter study. Timing of ACL reconstruction (within 6 weeks or after three months following injury) will be randomly determined. Patients are enrolled in 12 participating clinics.

### Intervention

Early ACL-reconstruction (< 6 weeks) vs delayed ACL-reconstruction (> 3 months)

### Study burden and risks

Results of this study will contribute to the optimization of the treatment of patients with an ACL injury. It is expected that the risks associated with participation in the study are negligible. The research involves only a change in timing of surgery (ACL reconstruction) that has proven to be effective and safe. A possible risk to participation in the study is the risk of artrofibrosis at an early ACL reconstruction. However, since a preoperative extension and flexion limitation is an exclusion criteria, it is expected that the probability of the occurrence of artrofibrosis in the group receiving early ACL reconstruction will be just as large as in the group operated at 3 months after injury. The risks associated with the measurements made in this study are negligible, since the measurements are similar to physical exercises and workouts that patients after ACL reconstruction perform during physiotherapy as part of their rehabilitation.

# 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**

- Active young (18 40) pivoting sportsmen/women or heavy duty workers, Tegner score > 5
- Isolated ACl injury
- Ambition to return to pre-injury level
- Fresh ACL rupture < 4 weeks
- Diagnosis of ACL-rupture by physical examination (Lachmann, pivot-shift) and/or MRI

## **Exclusion criteria**

- Re-injury ACL ipsilateral
- Additional contra- or ipsilateral injury, for example a fracture

- Multiple ligamentous injury (MCL-lesion, PCL-rupture, knee luxation, posterolateral instability)

- Previous traumasurgery lower extremity, for example pelvic, hip, knee or ankle
- Osteoartritis grade IV injured knee
- Accompanying neurovascular injury

- Loss of Extension > 10 degrees and/or Loss of Flexion > 20 degrees, not induced by a mechanical cause (meniscus interposition, cyclops). This can be diagnosed by MRI or

# Study design

## Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	09-04-2013
Enrollment:	150
Туре:	Actual

# **Ethics review**

Approved WMO Date:	05-03-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-03-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

# **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
Other	13793
ССМО	NL42380.042.12