

Research comparing acute ACL reconstruction and delayed ACL reconstruction.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23490

Source

Nationaal Trial Register

Brief title

RADAR

Health condition

timing of surgery
ACL rupture
ACL reconstruction
functional outcome

Sponsors and support

Primary sponsor: Prof. dr. R.L. Diercks

Dr. K. W. Wendt

Source(s) of monetary or material Support: Zon-MW

Intervention

Outcome measures

Primary outcome

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, which will be objectively measured with a sequence of hoptests.

Secondary outcome

Also, a costs effectiveness analysis associated with the ACL reconstruction and rehabilitation and costs associated (time off work, fysiotherapeutic costs, etc) will be performed.

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 usual timing. However, the evidence is scarce and no RCT has been conducted on this subject.

Study objective

Hypothesis 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

Measurements will be performed preoperatively, and after 6 weeks, 3 and 6 months postoperatively.

Intervention

Patients will be randomised in:

1. Early ACL reconstruction (<6 weeks after injury);
2. Delayed surgery, which is the usual timing of ACL reconstruction (> 3 months after injury).

Contacts

Public

Hanzeplein 1
Roeland Boer, den
Groningen
The Netherlands
+31 (0)6 41959335

Scientific

Hanzeplein 1
Roeland Boer, den
Groningen
The Netherlands
+31 (0)6 41959335

Eligibility criteria

Inclusion criteria

1. Active, pivoting sport player;
2. Age between 18 and 40;
3. Desire to return to pre-injury level;
4. Fresh ACL rupture (< 4 weeks);
5. Diagnosis with positive Lachmann/pivotshift and/or MRI.

Exclusion criteria

1. Re-injury ACL;
2. Concomitant lesion same/other site (for example a fracture);
3. Multiple ligamentous injury;

4. Chondropathy grade IV;

5. A persisting loss of extension of 10 degrees and flexion deficit of 20 degrees, not of cyclops or bucket-handle origin.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2013
Enrollment:	150
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

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
NTR-new	NL3553
NTR-old	NTR3703
Other	CCMO : 42380
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A