Computer Assisted Surgery versus conventional arthroscopic Anterior Cruciate Ligament reconstruction – a prospective randomised clinical trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26161

Source
NTR

Brief title
CAS versus conventional ACL reconstruction

Health condition

Anterior cruciate ligament rupture

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Planned tunnel position versus actual achieved tunnel position of the ACL transplant (by CT)

Secondary outcome

1. difference in change in IKDC
2. difference in change in KOOS
3. difference in change in knee pain (VAS for pain)
4. difference in change in knee complaints (Lysholm score)
5. difference in change in sport activity (Tegner score)
6. difference in change in objective instability of the knee (KT1000)
7. difference in change in objective muscle strenght (Biodex)
8. difference satisfaction of the treatment

Study description

Background summary

The most common reason for failure after an ACL reconstruction is a malposition of the new ACL transplant due to a malposition of the tibial tunnel and/ or femoral tunnel.
Since one year in the Erasmus MC Computer-assisted surgery (CAS) has become established for total knee replacement. There are less malpositions following CAS than after implantation by the conventional technique. Nowadays it’s possible to use CAS for ACL reconstruction. The main aim of this study is to compare the results of the ACL reconstruction following CAS with a conventional ACL reconstruction.

Study objective

An ACL reconstruction can take place more accurate with Computer Assisted Surgery than a conventional arthroscopic reconstruction with regard to tunnel position

Intervention

Arthroscopic ACL reconstruction, randomised in 45 conventional (usual care), and 45 CAS.

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Eligibility criteria

Inclusion criteria

1. All patients with an ACL rupture who are indicated for a reconstruction;
2. Age >18 yrs.

Exclusion criteria

1. Patients who are unable to understand Dutch written language;
2. Patients who are unable to follow the regular postoperative controls.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2006
Enrollment:	90
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-01-2007
Application type:	First submission

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	NL856
NTR-old	NTR870
Other	: N/A
ISRCTN	ISRCTN40231111

Study results

Summary results
N/A