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A study of three different fixation methods in anterior cruciate ligament reconstruction

Submission date
02/04/2020

Recruitment status
No longer recruiting

Registration date
17/04/2020

Overall study status
Completed

Last Edited
09/02/2024

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The anterior cruciate ligament (ACL) is a tough band of tissue joining the thigh bone to the shin bone at the knee joint. ACL injuries can be treated with reconstructive surgery removing what remains of the torn ligament and replacing it with a tendon from another area of the leg, such as the hamstring. The aim of this study is to compare the results of hamstring tendon ACL reconstructions with different fixation methods.

Who can participate?
Patients aged 18 to 50 with ACL injuries

What does the study involve?
Participants are randomly allocated into four different groups to be treated with different fixation methods. Hamstring tendons are used as a graft with every patient. Participants are followed up for 5 years to assess the stability of the operated knee.

What are the possible benefits and risks of participating?
Possible benefits are a stable knee. Possible risks are operative risks including infection.

Where is the study run from?
Orton Orthopaedic Hospital (Finland)

When is the study starting and how long is it expected to run for?
June 2001 to January 2016

Who is funding the study?
This work was supported by Orton research grants by the Ministry of Social Affairs and Health (Finland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A prospective randomized study of three hamstring fixation devices with a minimum 5-year follow-up

Study objectives
After 5 years of follow-up there is no difference in the outcome after either cross-pin or absorbable interference screw fixation in ACL (anterior cruciate ligament) reconstruction with hamstring tendon autografts.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/11/2015, The Hospital District of Helsinki and Uusimaa Operative Ethics Committee (Tynnyrintekijänkatu 1 C, Helsinki, Finland; +358 (0)50 428 7838; keskuskirjaamo@hus.fi), ref: 364/13/03/02/2015. TMK02 §219

Study design
Randomized controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anterior cruciate ligament injury

Interventions
Randomization will be done by sealed, numbered envelopes containing information of the treatment group. The study is a comparison of results of hamstring tendon ACL reconstructions with different fixation methods:
Group I: femoral Rigidfix cross-pins and a tibial expansion sheath with a tapered expansion screw Intrafix
Group II: femoral Rigidfix and tibial interference screw fixation with BioScrew
Group III: femoral BioScrew and tibial Intrafix fixation
Group IV: BioScrew fixation into both tunnels (tibia, femur)

Total duration of the treatment will be optimized for the patient's needs - the length of physiotherapeutic assistance some 6 weeks. The follow up is planned up to 5 years postoperatively. The last patients will be telephoned to collect the subjective results during winter 2015-2016.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Stability of the operated knee measured with Lachman, pivot-shift, and anteroposterior knee laxity tests, preoperative and at 1- and 2-year follow-ups

Key secondary outcome(s))
Patient satisfaction measured with Tegner, Lysholm, patellofemoral scores and IKDC questionnaires, preoperative and at 1- and 2-year follow-ups

Completion date
31/01/2016

Eligibility

Key inclusion criteria
1. Fresh or chronic injury (less than 5 years old)
2. Unilateral ACL tears
3. Female or male patient
4. Age range of 18 to 50 years

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
120

Key exclusion criteria
1. Interval between the injury and surgery over 5 years
2. ACL revision procedure
3. Concomitant grade 2-3 collateral or posterior cruciate ligament tear
4. Peripherally detached meniscal tear to be repaired
5. Outerbridge 3 to 4 chondral damage
6. Arthrosis of the knee

Date of first enrolment
01/08/2001

Date of final enrolment
31/08/2004

Locations

Countries of recruitment
Finland

Study participating centre
Orton Orthopaedic Hospital
Tenholantie 10
Helsinki
Finland
00280

Sponsor information

Organisation
Orton Orthopaedic Hospital

Funder(s)

Funder type
Government

Funder Name
Sosiaali- ja Terveysministeriö

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Arsi Harilainen (arsi.harilainen@orton.fi).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	2 year follow-up results	01/04/2009		Yes	No
Results article	5 year follow-up results	30/06/2022	01/07/2022	Yes	No
Results article	clinical follow up results for patient satifaction secondary outcomes	06/01/2024	09/02/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes