

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

Submission date 02/04/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 17/04/2020	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/02/2024	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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?

Dr Leena Metso
leena.metso@fimnet.fi

Contact information

Type(s)

Scientific

Contact name

Dr Leena Metso

ORCID ID

<https://orcid.org/0000-0003-2875-6478>

Contact details

Työpajankatu 14 A

Helsinki

Finland

00580

+358 (0)406700094

leena.metso@fimnet.fi

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

Patient satisfaction measured with Tegner, Lysholm, patellofemoral scores and IKDC questionnaires, preoperative and at 1- and 2-year follow-ups

Overall study start date

01/06/2001

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Target number of participants was 120, divided into 4 groups of 30 patients each

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

Sponsor details

Tenholantie 10

Helsinki

Finland

00280

+358-9-4748 2705

leena.ristolainen@orton.fi

Sponsor type

Hospital/treatment centre

Website

<http://www.orton.fi>

Funder(s)

Funder type

Government

Funder Name

Sosiaali- ja Terveysministeriö

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

30/04/2020

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 satisfaction secondary outcomes	06/01/2024	09/02/2024	Yes	No