

Results of tape locking screw device used in anterior cruciate ligament reconstruction: 2 years follow-up

Submission date 02/04/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/04/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 29/04/2020	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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 collect clinical follow-up data of the Tape Locking Screw™ (TLS™) technique in ACL reconstruction.

Who can participate?

Patients with an ACL injury

What does the study involve?

All patients undergo surgery with the Tape Locking Screw (TLS™) technique. There are clinical follow-ups at 1 and 2 years after the surgery, patients also filled in questionnaires.

What are the possible benefits and risks of participating?

Possible benefits include 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?

September 2007 to July 2012

Who is funding the study?

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

<http://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

Results of Tape Locking Screw™ in anterior cruciate ligament reconstruction: 2 years follow-up

Study objectives

This study is collecting clinical follow-up data of the Tape Locking Screw™ (TLS™) technique.

Ethics approval required

Old ethics approval format

Ethics approval(s)

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

Study design

Single-centre prospective clinical trial

Primary study design

Interventional

Secondary study design

Non randomised study

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

137 consecutive patients with an ACL injury were enrolled to be operated on with the TLS™ technique. Every ACL reconstruction was performed by the same orthopedic surgeon (AH) during the time period of November 2007 to July 2012. The results of Lysholm score, Tegner score, laxity, Lachmann test and pivot-shift tests were recorded at 1- and 2- years of follow-up. Patients were allocated consecutively in a single-centre hospital Orton in Helsinki Finland between November 2007 and July 2012. Clinical controls were at 1 and 2 years postoperatively.

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

30/09/2007

Completion date

30/07/2012

Eligibility

Key inclusion criteria

Patients with ACL injury

Participant type(s)

Patient

Age group

Mixed

Sex

Both

Target number of participants

The minimal target recruitment number was 120 patients

Total final enrolment

137

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/11/2007

Date of final enrolment

15/07/2012

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 (0)9 47481
leena.ristolainen@orton.fi

Sponsor type

Hospital/treatment centre

Website

<http://www.orton.fi>

Funder(s)

Funder type

Government

Funder Name

Sosiaali- ja Terveysministeriö

Alternative Name(s)

Ministry of Social Affairs and Health, Social- och Hälsovårdsministeriet

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Finland

Results and Publications

Publication and dissemination plan

Planned publication in spring 2020.

Intention to publish date

31/05/2020

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