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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

Registration date
29/04/2020

Overall study status
Completed

Last Edited
29/04/2020

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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 (Tynnyrintekijänkatu 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

Study type(s)
Treatment

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(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
30/07/2012

Eligibility

Key inclusion criteria
Patients with ACL injury

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

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

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

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