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Comparison of clinical results of anteromedial and transtibial femoral tunnel drilling techniques in knee reconstruction surgery

Submission date
31/12/2019

Recruitment status
No longer recruiting

Registration date
09/01/2020

Overall study status
Completed

Last Edited
05/06/2020

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Anterior cruciate ligament (ACL) reconstruction is a type of knee surgery to replace the ACL – one of the main ligaments in the knee. The ACL connects the thigh bone to the shin bone, and along with other ligaments in the knee, keeps the knee stable. A number of methods can be used to reconstruct an anterior cruciate ligament (ACL). The most common method is to use a tendon from elsewhere in the body to replace the ACL. The surgeon needs to drill a tunnel in the bone to pass the new tissue through.
The aim of this study is to compare two different drilling techniques in terms of the long term outcome on knee function.

Who can participate?
Patients who underwent knee reconstructive surgery at Orton Hospital in Helsinki Finland between May 1990 and December 2011

What does the study involve?
Retrospective data is gathered from patient records regarding the clinical outcomes of two different surgical techniques for knee reconstruction (anteromedial drilling and transtibial drilling).

What are the possible benefits and risks of participating?
None

Where is the study run from?
Hospital Orton, Invalid Foundation, Helsinki, Finland.

When is the study starting and how long is it expected to run for?
January 2006 to December 2013

Who is funding the study?
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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
9750/44

Study information

Scientific Title
A retrospective comparison of clinical results of anteromedial and transtibial femoral tunnel drilling in ACL reconstruction

Study objectives
Is there a clinical difference in results between anteromedial and transtibial femoral drilling in the reconstruction of anterior cruciate ligament?

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
Retrospective case control study

Primary study design
Observational

Secondary study design
Case-control 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 rupture

Interventions
Is there a clinical difference between anteromedial and transtibial tunnel drilling results in anterior cruciate ligament reconstruction at two year follow up. For this study we chose retrospectively 300 consecutive patients admitted to Orton Hospital, Helsinki Finland. They had been divided into two groups of 150 patients. The evaluation methods were clinical examination, knee scores (Lysholm, Tegner, IKDC) and instrumented laxity measurements (KT-2000™).

ACL ruptures were treated with an operation. 150 patients with anteromedial (AM) drilling and 150 with transtibial (TT) drilling. In the AM group the reconstructions were performed using semitendinosus graft with Tape Locking Screw (TLS™) technique or Retrobutton™ femoral and BioScrew™ tibial fixation with a semitendinosus-gracilis graft. In the TT group the fixation method used was Rigidfix™ femoral and Intrafix tibial fixation.

Patients were allocated consecutively in a single-centre hospital Orton in Helsinki Finland between May 1990 and December 2011. Clinical controls were at 1 and 2 years postoperatively. This is a retrospective study.

Intervention Type
Procedure/Surgery

Primary outcome measure

Recovery of knee function measured at one and two years post-operatively using:
1. Clinical examination
2. Knee scores (Lysholm, Tegner, IKDC)
3. Instrumented laxity measurements (KT-2000™)

Secondary outcome measures
Patient satisfaction measured using inteview at one and two years post-operatively

Overall study start date
01/01/2006

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Male and female gender, no data of the percentage is collected
2. No limitations, mean age of the patients was 34 years (12-64 years)
3. ACL reconstruction performed with meniscal and collateral surgery done if needed

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
Total number of patients recruited was 300. Revision ACL reconstruction was performed in 18 patients in the anteromedial group and in 17 in the transtibial group. These patients were excluded from the final evaluation leaving 132 patients in the anteromedial group and 133 patients in the transtibial group.

Total final enrolment
265

Key exclusion criteria
1. PCL reconstruction done at the same time or previously
2. Revision ACL surgery (exclusion from the final data analysis)

Date of first enrolment
15/05/1990

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Finland

Study participating centre
Hospital Orton, Invalid Foundation
Tenholantie 10
Helsinki
Finland
00280

Sponsor information

Organisation
Invalidisäätiö

Sponsor details
ORTON Orthopaedic Hospital, Invalid Foundation
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Sponsor type
Hospital/treatment centre

Website
https://www.orton.fi

ROR
https://ror.org/020vv3w23

Funder(s)

Funder type
Government

Funder Name

This work was supported by Orton research-grants by the Ministry of Social Affairs and Health, Finland.

Results and Publications

Publication and dissemination plan
This article will be sent for evaluation in an orthopaedic journal in January 2020.

Intention to publish date
16/01/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Data is available from Arsi Harilainen, arsi.harilainen@orton.fi, type of data: BMDP statistics, data available at any time for 10 years. Access considered upon request. Raw data can be provided. Sharing the data with the third party has not been discussed with participants. Data is anonymised and there are no legal restrictions.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/06/2020	05/06/2020	Yes	No