

Preservation technique of ruptured anterior cruciate ligament (ACL)

Submission date
23/04/2011

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
24/05/2011

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
24/05/2011

Condition category
Injury, Occupational Diseases, Poisoning

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

A single-centre, prospective, randomised controlled study comparing the common treatment of anterior cruciate ligament repair (semitendinosus grafting) to preservation and healing of the torn ligament using the dynamic intraligamentary stabilisation system

Study objectives

This study compares in a prospective randomised trial a novel technique to preserve the ruptured anterior cruciate ligament in comparison to the established technique of replacing the torn ligament with a semitendinosus graft. Especially the stability of the knee is compared after 3, 6 and 12 months and the clinical outcome is measured using the IKDC and Lysholm score. The level of sportive activity is assessed according to the Tegner protocol.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Bern Cantonal Ethics Commission (Kantonale Ethikkommission Bern) (KEK) approved on 07/03 /2009, KEK Ref.-Nr. KEK-BE: 048/09

Study design

Single-centre prospective randomised controlled study

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 contact kathrinaeschlimann@sonnenhof.ch to request a patient information sheet

Health condition(s) or problem(s) studied

Anterior cruciate ligament (ACL) injury

Interventions

100 patients are subsequently operated after ACL injury. After a prospective randomisation the patient are either treated with an established semitendinosus transplant or with the new dynamic intraligamentary stabilisation technique.

The idea of the new technique is, that the torn ligament is preserved and brought to stable healing without replacement. Thereby a spring-screw mechanism, which is implanted into the tibia pulls the knee in a constant posterior translation. This internal stabilisation of the knee enables the ligament in combination with a microfracturing of the notch and PRF (platelet rich

fibrin) induction to heal. Healing is measured 3, 6 and 12 months after surgery by magnetic resonance imaging (MRI) and mechanical translation measurement of the knee. Additionally clinical and sportive outcome is measured using the Lyshom, IKDC and Tegner score.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Healing of ACL in magnetic resonance imaging (MRI)
2. Lysholm score, Tegner score, International Knee Documentation Committee (IKDC) score

Measured 3, 6 and 12 months after surgery.

Secondary outcome measures

1. Length of hospital stay
2. Time of rehabilitation
3. Satisfaction with results (VAS 0: completely unsatisfied, 10: completely satisfied)

Overall study start date

01/08/2009

Completion date

01/01/2012

Eligibility**Key inclusion criteria**

1. Fresh ACL rupture (injury not older than 14 days)
2. Age under 45 years
3. No previous surgery on the injured knee
4. Regular participation in sports requiring pivoting of the knee joint

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

100 patients

Key exclusion criteria

1. Age over 45
2. Previous injury to that knee, injury older than 14 days
3. Non-sportive patients (Tegner score less than 3)

Date of first enrolment

01/08/2009

Date of final enrolment

01/01/2012

Locations

Countries of recruitment

Switzerland

Study participating centre

Freiburgstrasse

Bern

Switzerland

3011

Sponsor information

Organisation

Swiss National Insurance Association (SUVA) (Switzerland)

Sponsor details

SUVA - Fluhmattstrasse 1

Luzern

Switzerland

6002

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Sponsor type

Government

ROR

<https://ror.org/053ae3r23>

Funder(s)

Funder type

Government

Funder Name

Swiss National Insurance Association (SUVA) (Switzerland)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration