ISRCTN89368687 https://doi.org/10.1186/ISRCTN89368687

Preservation technique of ruptured anterior cruciate ligament (ACL)

Submission date	Recruitment status	[ ] Prospectively registered
23/04/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/05/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/05/2011	Injury, Occupational Diseases, Poisoning	[ ] 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. Additionaly 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 sastisfied)

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
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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