

Preservation technique of ruptured anterior cruciate ligament (ACL)

Submission date 23/04/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 24/05/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 24/05/2011	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
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Stefan Eggli

Contact details
Freiburgstrasse
Bern
Switzerland
3011
stefaneggli@sonnenhof.ch

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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 Lysholm, IKDC and Tegner score.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

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

Funder(s)

Funder type

Government

Funder Name

Swiss National Insurance Association (SUVA) (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes