

# Preservation technique of ruptured anterior cruciate ligament (ACL)

<b>Submission date</b> 23/04/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 24/05/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 24/05/2011	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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 Lyshom, 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