

Screws versus Pins for Optimal Transplant fixation in anterior cruciate ligament replacement surgery

Submission date 29/11/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 06/01/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/09/2009	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Acronym

SPOT

Study objectives

Added 13/08/09:

The RigidFix® system preserves graft tension gained during surgery, and leads to lower KT-1000 arthrometer side-to-side differences than the BioCryl® screw after six months of follow-up.

As of 13/08/09 this record has been extensively updated. All updates appear in the relevant field with the above update date.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised active controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Reconstructive surgery for anterior cruciate ligament (ACL) deficiency

Interventions

Patients will undergo standardised, arthroscopic ACL replacement by four-stranded hamstring tendon grafts. During surgery, participants will be randomised to transplant fixation by resorbable poly-L-lactide pins (experimental group) or poly-L-lactide/hydroxyapatite screws (control group). No other changes will apply in the treatment protocol. We will compare the residual anterior knee laxity at 3- and 6- months-follow-up between both methods.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

Added 13/08/09

Side-to-side (repaired to healthy knee) difference in anterior translation as measured by the KT-1000 arthrometer at a defined load (89 N) six months after surgery

Key secondary outcome(s))

Added 13/08/09:

1. Generic and disease-specific measures of quality of life evaluated by:

1.1. Lysholm scale

1.2. Tegner score

1.3. International Knee Documentation Committee evaluation form (IKDC) German translation

2. Magnetic resonance imaging morphology of transplants and devices

Completion date

31/12/2005

Eligibility

Key inclusion criteria

Female and male patients >18 years with closed tibial metaphyses, a first event of a unilateral ACL rupture, proven by arthroscopy or magnetic resonance imaging (MRI) scanning, scheduled for ACL replacement surgery.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/12/2004

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

Germany

Study participating centre

Clinical Epidemiology Division
Berlin
Germany
12683

Sponsor information

Organisation

Emergency Hospital, Berlin (Unfallkrankenhaus Berlin) (Germany)

ROR

<https://ror.org/011zjcv36>

Funder(s)

Funder type

Other

Funder Name

No sponsoring by third parties

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?
Results article	results	01/09/2009		Yes	No
Protocol article	protocol	21/02/2005		Yes	No