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

Submission date 29/11/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/01/2005	**Overall study status** Completed	
Last Edited 03/09/2009	**Condition category** Surgery	

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

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/12/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
54

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)

Sponsor details
Warener Str. 7
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12683
stengeldirk@aol.com

Sponsor type
Hospital/treatment centre

Website
http://www.ukb.de

ROR
https://ror.org/011zjcv36

Funder(s)

Funder type
Other

Funder Name
No sponsoring by third parties

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	21/02/2005		Yes	No
Results article	results	01/09/2009		Yes	No