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Anterior Cruciate Ligament (ACL) Reconstruction using two different types of Femoral Fixation i.e. Mitec Rigidfix femoral polylactide (PLA) cross pin and the Anthrex Bio Transfix implant

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 13/02/2017	**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
N0020129460

Study information

Scientific Title
Anterior Cruciate Ligament (ACL) Reconstruction using two different types of Femoral Fixation i. e. Mitec Rigidfix femoral polylactide (PLA) cross pin and the Anthrex Bio Transfix implant

Study objectives
Is there any difference in the outcome of the ACL reconstruction using two types of femoral fixation?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

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 use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Surgery: Anterior cruciate ligament reconstruction

Interventions
Patients with ACL deficiency to be reconstructed using hamstring graft (4 strands) with two types of fixture.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
International Knee Documentation Committee (IKDC) scoring system - tagner scoring system

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2003

Completion date
01/09/2006

Eligibility

Key inclusion criteria
100 ligament reconstruction patients

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
100 patients - 50 in each group

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/2003

Date of final enrolment
01/09/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oldchurch Hospital
Romford
United Kingdom
RM7 0BE

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Barking, Havering and Redbridge Hospitals NHS Trust (UK)

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