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A randomised prospective comparison of two anterior cruciate ligament graft fixation techniques

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/02/2020	Surgery	[ ] Record updated in last year

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
N0234098041

Study information

Scientific Title
A randomised prospective comparison of two anterior cruciate ligament graft fixation techniques

Study objectives
Comparing two different methods of fixing an anterior cruciate ligament (ACL) graft to the tibia in patients undergoing ACL reconstruction. To identify any difference in knee stability, range of movement or return to pre-injury levels of activity between the two groups.

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

Health condition(s) or problem(s) studied
Anterior cruciate ligament (ACL) graft

Interventions
Randomised controlled trial. Patients randomised to one of two methods of fixation of ACL grafts.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Post operative knee laxity

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2001

Completion date
31/05/2003

Eligibility

Key inclusion criteria
80 Patients undergoing ACL reconstruction.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
80

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/06/2001

Date of final enrolment
31/05/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Orthopaedic Surgery
Bristol

United Kingdom
BS16 1LE

Sponsor information

Organisation
Department of Health (UK)

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

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
North Bristol 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