ISRCTN30554985 https://doi.org/10.1186/ISRCTN30554985

Investigation into patient characteristics and treatment factors associated with short-term and medium-term outcome following Anterior Cruciate Ligament Reconstruction

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 23/05/2016	**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

Protocol serial number
N0209181918

Study information

Scientific Title

Investigation into patient characteristics and treatment factors associated with short-term and medium-term outcome following Anterior Cruciate Ligament Reconstruction

Study objectives
What are the factors pre-operatively, intra-operatively and post-operative and related to patient characteristics that have the most influence on outcomes of ACL reconstruction? Particular focus on post operative/rehabilitation factors (knee swelling and initial rehabilitation) and patient psychological factors (adherence to rehabilitation, motivation and sense of control).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 28/08/09:
Joint UCL/UCLH Committees on the Ethics of Human Research (Committee A), Research & Development Directorate, 1st Floor Maple House, 149 Tottenham Court Road, London W1P 9LL. REC reference number: 05/Q0505/120. Meeting date 26th January 2006, approval letter dated 9th February 2006.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Interventions
Randomised between 2 groups: normal management vs measures to reduce swelling

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
Questionnaire - International Knee Documentation committee (IKDC) form

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/03/2010

Eligibility

Key inclusion criteria
100 patients recruited from UCLH Foundation Trust, in need of Arthroscopic anterior cruciate ligament reconstruction (ACL) for uncomplicated ACL reconstruction.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Concurrent surgery (meniscus repair, posterior cruciate ligament reconstruction, other ligament injuries)
2. Patients with gross pre-operative swelling/inflammation, pre-operative loss of normal movement (esp. leg straightening), heavy manual/impact type of work, compulsory return to work before 4 weeks post op).

Date of first enrolment
01/04/2006

Date of final enrolment
01/03/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Trauma & Orthopaedics
London
United Kingdom
NW1 2BU

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
UCL Hospitals NHS Foundation Trust (UK), NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration