

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
Registration date 28/09/2007	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 23/05/2016	Condition category Surgery	☐ Individual participant data ☐ 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

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.

Study design

Randomised controlled trial

Primary study design

Interventional

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**

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