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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Please contact Bruce.Paton@uclh.nhs.uk or Bruce Paton, Extended Scope Practitioner, Physiotherapy Dept., University College Hospital, 235 Euston Road, London NW1 2BU.

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 measure
Questionnaire - International Knee Documentation committee (IKDC) form

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2006

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
100

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
England

United Kingdom

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

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

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

Funder(s)

Funder type
Government

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

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