

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

<b>Submission date</b> 28/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 23/05/2016	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## 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