The effect of prehabilitation on the outcome of anterior cruciate ligament reconstruction

Submission date 12/01/2011	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 31/01/2011	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 30/07/2013	Condition category Injury, Occupational Diseases, Poisoning	Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

The effect of prehabilitation on the outcome of anterior cruciate ligament reconstruction: a two centre prospective, single surgeon, randomly allocated study

Study objectives

To determine whether prehabilitation would result in equal quadriceps strength 3 month post anterior cruciate ligament (ACL) reconstruction.

As of 20/09/2011 the anticipated end date for this trial has been extended from 30/06/2011 to 30/06/2012.

Ethics approval required

Old ethics approval format

Ethics approval(s)

 Cappagh National Orthopaedic Hospital Research Ethics Committee approved on the 1st December 2009 (ref: JOB.10.2009.28)
 Sports Surgery Clinic Research and Ethics Committee approved on the 8th February 2010

Study design

Single surgeon multicentre prospective randomised controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Anterior cruciate ligament tear

Interventions

This interventional trial will recruit 30 patients: 15 in the prehabilitation exercise group, 15 control patients recieving standard pre- and post-operative care. The prehabilitation group will recieve 6 weeks pre-operative physiotherapy programme comprising of 2 gym and 2 home sessions per week.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Isokinetic quadriceps strength testing

2. Magnetic resonance imaging cross-sectional area of the quadriceps (MRI CSA)

3. Physical performance test: single leg hop test and in-line lunge

4. Disease specific questionnaire: Modified Cincinnatti Knee Score, Tegner Lysholm Knee Score, Tegnaer Activity Scale

5. Muscle biopsy of quadriceps: looking for down-regulation of muscle atrophy genes and upregulation in IGF-1 pathways in muscle hypertrophy

Patients will undergo all the above test at time of recruitment, 6 weeks post exercise and 3 months postoperatively.

6. Time to return to sports activities

Secondary outcome measures

1. To determine the effect of a pre-operative exercise programme on isokinetic hamstring strength

2. To assess the validity, reliability and responsiveness of:

- 2.1. Isokinetic dynamometry
- 2.2. Physical performance tests
- 2.3. Questionnaires

Overall study start date

13/01/2011

Completion date

30/06/2012

Eligibility

Key inclusion criteria

1. Patients with isolated anterior cruciate ligament tear

2. Males aged 18 - 40 years

Participant type(s)

Patient

Age group

Adult

Lower age limit 18 Years

Sex Male

Target number of participants 30

Key exclusion criteria

1. Patients with age less than 18 or over 40 years

2. Patients living outside Greater Dublin area (for practical reasons regarding exercise supervision)

3. Patients with associated fractures, meniscal repair and collateral ligament injury

4. Patients with co-morbidities (contra-indication to relatively high physical exertion)

Date of first enrolment

13/01/2011

Date of final enrolment

30/06/2012

Locations

Countries of recruitment Ireland

Study participating centre Cappagh National Orthopaedic Hospital Dublin Ireland 11

Sponsor information

Organisation Cappagh National Orthopaedic Hospital (Ireland)

Sponsor details Finglas Dublin Ireland 11

Sponsor type Hospital/treatment centre

Website http://www.cappagh.ie

ROR https://ror.org/03vc5bf16

Funder(s)

Funder type Other

Funder Name Investigator initated and funded (Ireland)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	01/09/2013		Yes	No