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

Submission date	Recruitment status
12/01/2011	No longer recruiting
Registration date	**Overall study status**
31/01/2011	Completed
Last Edited	**Condition category**
30/07/2013	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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11

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)
1. Cappagh National Orthopaedic Hospital Research Ethics Committee approved on the 1st December 2009 (ref: JOB.10.2009.28)
2. 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 up-regulation 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?
Results article	results	01/09/2013		Yes	No