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The effect of home electrical stimulation and intra-operative femoral nerve blockage on outcomes after anterior cruciate ligament reconstruction

Submission date
18/03/2015

Recruitment status
No longer recruiting

Registration date
16/07/2015

Overall study status
Completed

Last Edited
04/09/2019

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
An anterior cruciate ligament injury is the over-stretching or tearing of the anterior cruciate ligament (ACL) in the knee. Over 200,000 ACL injuries occur in the United States every year. Thigh muscle weakness and poor function are common following ACL injury. The recovery of strength is particularly important because weakness of the quadriceps (thigh) muscles is related to poorer function after ACL surgery. Specifically, better quadriceps strength prior to surgery is related to better function after surgery. Therefore, improving muscle strength before surgery may actually improve your function after surgery. Neuromuscular electrical stimulation (NMES) is used in rehabilitation, and is helpful in improving muscle strength when used in combination with strengthening exercises after ACL surgery. The effects of NMES used before ACL surgery have not yet been examined. The purpose of this study is to test how electrical muscle stimulation affects the recovery of athletes who have had an ACL injury.

Who can participate?
Athletes aged 14-49 with an ACL injury.

What does the study involve?
If you are enrolled in this study, you will be randomly assigned by a computer to receive one of two types of NMES to your quadriceps muscles during your rehabilitation. NMES is applied to your muscles through surface pads that transmit low levels of electrical current from a battery-powered unit. You will be sitting or lying down during the treatment, and you will not have to do any exercises while you are receiving NMES. After your ACL surgery, you will have supervised physical therapy, just like you would if you were not involved in a research study.

What are the possible benefits and risks of participating?
This treatment will address the issues you will have with knee range of motion, strength, and function. Your participation will help us develop effective rehabilitation programs for athletes who need ACL surgery. The risk of physical injury or muscle fatigue or discomfort to you during

treatment or testing is minimal. There is a minimal risk of injury from a fall or improper landing during the box drop tests which measures knee motion. During NMES, your muscles may produce strong contractions that feel like muscle cramping, or a 'Charlie Horse,' and may last up to 15 seconds. You may experience muscle soreness following treatment that is similar to what you would experience following rigorous exercise, which should go away within 1-2 days. There is also a small risk of skin irritation or mild muscle discomfort from use of the NMES unit. Certain implants, devices, or objects may be hazardous to you and/or may interfere with the magnetic resonance imaging (MRI) procedure. Prior to your MRI, an MRI technologist or Radiologist will consult with you to make sure that you can safely undergo the MRI testing. Femoral nerve blocks are used during surgery to help control post-operative pain, in addition to medications your doctor will prescribe. You will be closely monitored following surgery by both your surgeon and your physical therapist to make sure that your recovery is as comfortable as possible.

Where is the study run from?
OSU Sports Medicine (USA).

When is the study starting and how long is it expected to run for?
From January 2012 to September 2018.

Who is funding the study?
Empi, Inc. (USA).

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2011H0420

Study information

Scientific Title
The effect of home electrical stimulation and intra-operative femoral nerve blockage on outcomes after anterior cruciate ligament reconstruction: a prospective, randomized controlled trial with cross-over design

Study objectives
The use of neuromuscular electrical stimulation after ACL (anterior cruciate ligament) reconstruction is described in the literature; however, literature on the use of home NMES and its effect on quadriceps strength and cross-sectional area after ACL reconstruction is scant. In addition, there is little discussion in the literature of how quadriceps function is affected by the use of a femoral nerve block during the surgical intervention.

The purpose of this study is to evaluate the effect of pre-surgical and post-surgical home electric muscle stimulation and intra-operative femoral nerve block use on outcomes after ACL reconstruction. The application will test two general hypotheses. The first hypothesis is that home neuromuscular stimulation as an adjunct to the current standard of care following ACL injury and reconstruction will improve quadriceps strength, cross-sectional area and function after ACL reconstruction. A second hypothesis is that the utilization of a femoral nerve block intra-operatively will retard quadriceps strength return and outcomes after ACL reconstruction.

The first specific aim is to determine the effect of pre-operative home neuromuscular electric stimulation on quadriceps femoris muscle strength and morphology after ACL injury (hypothesis: patients with ACL injury who utilize home NMES pre-operatively will experience a reduction in quadriceps atrophy and improved quadriceps femoris strength compared to those who do not use home NMES pre-operatively).

The second specific aim is to determine the effect of an intra-operative femoral nerve block during ACL reconstruction on quadriceps femoris muscle strength post-operatively (hypothesis: intra-operative use of femoral nerve block during ACL reconstruction will result in an initial short-term quadriceps muscle strength deficit compared with patients who do not receive a femoral nerve block).

The third specific aim is to determine the effect of post-operative home neuromuscular electric stimulation on quadriceps femoris muscle strength and morphology after ACL injury (hypothesis: patients after ACLR who utilize home NMES post-operatively as an adjunct to standard post-operative care will experience a reduction in quadriceps atrophy and improved quadriceps femoris strength compared with those who do not use home NMES post-operatively).

Ethics approval required
Old ethics approval format

Ethics approval(s)

The Ohio State University Office of Responsible Research Practices, Protocol Number 2011H0420

Study design
Prospective randomized controlled trial with cross-over design

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Athletes with a torn ACL (anterior cruciate ligament)

Interventions
Each subject will receive the medical and rehabilitative standard of care following ACL injury from OSU sports medicine. Medically, if the patient elects to undergo surgical intervention, they will be scheduled for surgery a minimum of 2 weeks following the initial visit and receive an ACLR with hamstrings autograft performed by Drs. Kaeding, Flanigan, or Jones. The current average time from diagnosis to surgical intervention in Drs. Kaeding, Flanigan, and Jones's clinic is 2 weeks. Prior to surgery, if the patient presents with impairments which are determined to be a risk for post-operative complications (knee flexion contracture, loss of motion, significant residual effusion, reduced neuromuscular performance) (Eitzen 2009, Mauro 2008, Mohtadi 1991, Shelbourne and Patel 1999), the patient will be referred to pre-operative Physical Therapy (PT) to address these impairments before surgery. If the patient does not present with any of these impairments, no pre-operative clinically-administered PT will be recommended, consistent with the current standard of care.

At the time of randomization into each e-stim cohort, the subjects will also be randomized into a femoral nerve block (FNB) vs. no femoral nerve block (no FNB) group, which will yield eight, evenly allocated groups. The surgeon and attending anesthesiologist will be notified of the FNB assignment of each participant at the time of the initial randomization. Subjects in the FNB group will be scheduled to receive a FNB during the surgical intervention. Those subjects who are assigned to the no FNB group will not receive this intervention at the time of the ACL reconstruction. Subjects will be blinded to their nerve block group assignment.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Disease-specific questionnaires, including the International Knee Documentation Committee (IKDC), Knee Osteoarthritis Outcome Score (KOOS), the Marx Activity Scale, and the SF-36

Health Survey
2. Magnetic resonance imaging (MRI) - in addition to the six weeks post-operative clinical assessment, the subjects will undergo a post-operative MRI of the knee and thigh regions, bilaterally. The purpose of the MRI is to assess the cross-sectional area of the quadriceps musculature post-operatively compared to the contralateral limb to report on the change in the muscle size during the course of the intervention.

Secondary outcome measures
1. Clinical assessment - each subject will undergo repeated measures of standard clinical assessment tools to longitudinally assess progress prior to ACLR and throughout the post-operative rehabilitation course. Clinical and functional variables of interest include:
1.1. Subject demographics and history of injury (i.e., age, gender, date of injury, mechanism of injury, sports participation)
1.2. Knee range of motion, knee joint effusion, thigh circumference
1.3. Quadriceps and hamstrings strength and single leg hop testing
These measures, unless otherwise indicated, will be assessed at the time of initial diagnosis, immediately prior to surgery, and at 2, 6, 12, 26, 52 and 106 weeks post-operative.
2. Biomechanical assessment – all participants will undergo three-dimensional motion analysis testing to capture the kinematics and kinetics of the lower extremities and trunk, both pre-operatively and following their six-week post-operative clinical assessment. Walking gait and landing tasks will be assessed at regular intervals from pre- to post-surgery; no landing tasks will be examined within the first 12 weeks after ACLR. All subjects must be medically cleared

Overall study start date
06/01/2012

Completion date
15/09/2018

Eligibility

Key inclusion criteria
Inclusion criteria for athletes with ACL reconstruction:
1. 14-49 years old
2. Prior to injury, athletes participated in level I/II cutting, pivoting, jumping, and lateral movement sports at least 50 hours/year
3. Acute unilateral ACL tear with plan for reconstruction with hamstring autograft
4. All eligible patients must provide written informed consent (assent for children ages 14-17) prior to participation

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants

Key exclusion criteria
Exclusion criteria for athletes with ACL reconstruction:
1. Prior ACLR (either ipsilateral or contralateral)
2. Patients who have a medical history that includes serious lower extremity injury or surgery (i. e., anterior cruciate ligament reconstruction, fractures) that may affect performance of dynamic jumping tasks
3. Patients who have a medical history of heart disease, ischemia of the lower limbs, arterial /circulation problems, rheumatic disease, epilepsy, any infectious disease, or anyone who has a pacemaker, defibrillator, or any other kind of electrical or metal implants
4. Patients who medically necessitate immediate (less than 2 weeks) surgical intervention to address secondary injury as determined by MD
5. Women who are currently pregnant
6. Patients who will not be in the Columbus area for 2 years

Date of first enrolment
06/01/2012

Date of final enrolment
16/08/2016

Locations

Countries of recruitment
United States of America

Study participating centre
OSU Sports Medicine
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Sponsor information

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
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Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository