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Is quadriceps tendon a better choice than hamstring tendons for repairing anterior cruciate ligament lesion?

Submission date
18/08/2015

Recruitment status
No longer recruiting

Registration date
25/08/2015

Overall study status
Completed

Last Edited
04/02/2019

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
The anterior cruciate ligament (ACL) is a tough band of tissue in the middle of the knee, preventing the shin bone (tibia) from sliding out in front of the thigh bone (femur). ACL injuries are one of the most common types of knee injuries, which usually occur during high-intensity sports such as football or basketball. They happen when the ACL in the knee is over-stretched or torn, which causes the knee to become very unstable and can make some types of movement very difficult. There are various surgical and non-surgical treatments available for people with an ACL injury, however when the tear is particularly bad, reconstructive surgery is often recommended. In this type of surgery, the doctor will replace the torn ligament with living tissue from elsewhere in the body (autograft). In most cases, the graft is taken from the hamstring tendons at the back of the thigh, however in some cases, a quadriceps tendon which runs from the kneecap into the thigh. The aim of this study is to compare the level of pain after surgery, and the short-term results for these two types of graft.

Who can participate?
Patients with ACL injury between 16-50 years of age.

What does the study involve?
Patients who are suitable for ACL repair surgery are randomly assigned into two groups. The first group receive a free quadriceps tendon autograft (taken from the same knee, just above the kneecap). The second group receive a quadrupled hamstring autograft (taken from the same knee, just beneath the kneecap). All patients are started on the same pain-relief regime one hour after surgery, and are asked to rate their pain intensity using a scale of 0-100 (with 0 being no pain, and 100 being severe pain) within the first 12 hours post-op, between 12-24 hours post-op, and between 24-48 hours post-op. The patients are also asked to complete questionnaires about their recovery after 6 weeks, 3 months, and 6 months after surgery.

What are the possible benefits and risks of participating?
There is no real benefit for participants, other than receiving treatment to help their condition. The risks of participating are the general risks surgical complications (infection, bleeding, surgical wound complication).

Where is the study run from?
University of Medicine and Pharmacy Cluj-Napoca (Romania)

When is the study starting and how long is it expected to run for?
October 2013 to May 2015

Who is funding the study?
University of Medicine and Pharmacy Cluj-Napoca (Romania)

Who is the main contact?
Mr Cristian Buescu

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
2015-003367-11

Protocol serial number
298

Study information

Scientific Title
Anterior cruciate ligament reconstruction with free quadriceps versus quadrupled hamstring autografts

Study objectives

The use of free quadriceps (FQ) will be less painful and will reduce analgesic use compared to semitendinos and gracilis (STG) in anterior cruciate ligament reconstruction, and that there will be no significant difference in short-term clinical results.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Iuliu Hatieganu University of Medicine and Pharmacy Ethics Committee, 29/07/2014, ref: 298/28.07.2014

Study design
Prospective longitudinal randomized parallel trial.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anterior cruciate ligament chronic injury

Interventions
We performed arthroscopic anatomic single-bundle anterior cruciate ligament reconstruction using either free quadriceps tendon autograft or quadrupled hamstring autograft (semitendinosus and gracilis tendons) .
A multimodal analgesic postoperative regimen was started 1 hour after surgery and consisted of acetaminophen (Paracetamol, Terapia-Ranbaxy, Cluj-Napoca, Romania) 500 mg per os (po) and ketorolac tromethamina (Ketorol, Dr. Reddy's Lab. (UK) LTD.) 15mg intravenous (iv) every 8 hours, for the first 49 postoperative hours. Rescue analgesia was provided with tramadol (Aliud® Pharma GmbH & Co. KG, Gottlieb-Daimler-Str. 19, D-89150 Laichingen, Germany) 30 mg iv bolus when patients declared pain scores of 30 or more on the Visual Analog Scale (VAS).

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Postoperative pain intensity was evaluated using the Visual Analog Scale, ranging from 0 to 100, with 0 to 30 considered mild pain, 30 to 70 moderate pain and over 70, severe pain.
2. Time to the first rescue analgesic requirement, the number of doses of tramadol and the pain score were recorded. The postoperative period was split three-way (first 12 hours post-op, 12-24 hours post-op, 24-48 hours post-op).

Key secondary outcome(s))
Follow-ups made at 6 weeks, 3 and 6 months after surgery with clinical assessment and Tegner and Lysholm self-evaluation questionnaires.

Completion date
20/05/2015

Eligibility

Key inclusion criteria
1. Aged between 16-50 years
2. Schedules for ACL repair.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Lesions older than 2 years, associated meniscus or other ligament lesion that required surgical management
2. Previous surgeries on the same knee.
3. Patients with chronic pain or hepatic impairment
4. Alcoholics or drug abusers.

Date of first enrolment
15/11/2013

Date of final enrolment
20/11/2014

Locations

Countries of recruitment
Romania

Study participating centre
University of Medicine and Pharmacy Cluj-Napoca
Orthopedics and Trauma Clinic
Cluj-Napoca
Romania
400132

Sponsor information

Organisation
University of Medicine and Pharmacy Cluj-Napoca

ROR
https://ror.org/051h0cw83

Funder(s)

Funder type
University/education

Funder Name
University of Medicine and Pharmacy Cluj-Napoca

Funder Name
Clinical Emergency County Hospital of Cluj

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes