

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/08/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/02/2019	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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

Contact name

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Additional identifiers

EudraCT/CTIS number

2015-003367-11

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 semitendinosus 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

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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 tromethamine (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 measure

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).

Secondary outcome measures

Follow-ups made at 6 weeks, 3 and 6 months after surgery with clinical assessment and Tegner and Lysholm self-evaluation questionnaires.

Overall study start date

20/10/2013

Completion date

20/05/2015

Eligibility**Key inclusion criteria**

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

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

60 patients: 30 in each group

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

Sponsor details

8 Victor Babes st

Cluj-Napoca

Romania

400012

Sponsor type

University/education

Website

www.umfcluj.ro

ROR

<https://ror.org/051h0cw83>

Funder(s)**Funder type**

University/education

Funder Name

University of Medicine and Pharmacy Cluj-Napoca

Funder Name

Results and Publications

Publication and dissemination plan

As data collection is finished, the article is prepared for submission to BMC: Journal of Orthopedic Surgery and Research.

Intention to publish date

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