Autologous conditioned plasma injection for acute hamstring muscle injury.

Published: 11-02-2011
Last updated: 19-03-2025

In this study two treatment groups will be compared: ACP injection in combination with exercise therapy and placebo injection in combination with exercise therapy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON37939

Source
ToetsingOnline

Brief title
Dutch Hamstring Injection Therapy (HIT) study

Condition

- Muscle disorders

Synonym
hamstring rupture, hamstring strain

Research involving
Human

Sponsors and support

Primary sponsor: Arthrex Medizinische Instrumente GmbH
Source(s) of monetary or material Support: Arthrex;fabrikant ACP

Intervention

Keyword: ACP injection, hamstring, injury, muscle rupture

Outcome measures

Primary outcome

Time to return to full sports activity; both training or match play.

Secondary outcome

Recovery assessed with a sevenpoints Likert scale, hamstring force, recurrent hamstring lesions, maximal and mean pain score in rest and during sprinting assessed with the visual analogue scale (VAS), pain with isometric contraction against resistance, length of pain area during palpation, clinical hamstring tests (passive straight leg raising, active knee extension, active slump test, taking shoe out sign), clinical sacroiliacal test (Stork test, multi test regime score, Gillet test), hip- and knee range of motion, functional outcome scores, subjective patient satisfaction, recovery of hamstringlesion on MRI (with reservation of financing), prediction of patient and sports physician for time to return to sports and prediction of the patient of the used intervention (ACP or placebo). Follow-up will be performed after 1, 3, 4, 6, 8, 10, 16, 26 and 52 weeks.

Study description

Background summary

Muscle injuries account for up to 30% of injuries sustained in a sports event. In soccer, muscle injuries mostly occur in the calf and thigh. When injured, usually the RICE principle (rest, ice, compression, elevation) is practised, NSAID's are supplied and exercise therapy is given. However, there is little scientific evidence for the effectiveness of therapeutic interventions in muscle injuries.
In the last decade research has focussed on developing new treatment options for muscle injuries, including the use of growth factors. Research has showed

that myoblasts can be proliferated by growth factors. Growth factors are present in autologous conditioned plasma (ACP). Injection of ACP has shown to increase regeneration in deliberatly injured muscle in animals.
Only two studies examined the effect of ACP in human muscle injuries in relatively small heterogenous group of patients. Both studies showed that patients treated with ACP injections recovered faster from injury than patients in the control group.

Study objective

In this study two treatment groups will be compared: ACP injection in combination with exercise therapy and placebo injection in combination with exercise therapy.

Study design

Double blind, randomized controlled trial comparing two treatment groups.

Intervention

Both the intervention group as the control group will have exercise therapy with a fysiotherapist. The intervention group is treated with ACP injection maximal 5 days after injury and the control group will recieve placebo injection maximal 5 days after injury (randomized and double blind). A second injection is performed 5-7 days after the first injection. Injections are performed ultrasound guided in the lesion of the hamstring muscle.

Study burden and risks

The intramuscular injections can be painfull, but usually less painfull than injections in tendons. A hematoma can occur. In previous studies with comparable therapeutic interventions complications has never been described and worsening of the muscle lesion is not reported. However, it is not possible to say with certainty that these results also account for injection in the hamstring.
After inclusion during one year there are 9 follow-up moments: three on the policlinic (about 1 hour) and six by phone (about 20 minutes).

Contacts

Public
Arthrex Medizinische Instrumente GmbH

Carl-Zeiss-Str. 8

Garching 85748
DE
Scientific
Arthrex Medizinische Instrumente GmbH

Carl-Zeiss-Str. 8
Garching 85748
DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1.Clinical diagnosis of an acute hamstring injury, defined as:
- anamnestic acute injury
- anamnestic pain in posterior thigh
- localised pain during palpation of hamstring muscle
- localised pain during passive straight leg raising
- increasing pain during isometric contraction
AND
2.Hamstring lesion proven on MRI (increased signal in injured muscle on T2 and/or STIR)
AND
3. First injection will be performed maximal 5 days after injury
AND
4. Informed consent
AND
5. Age 18-50 year

Exclusion criteria

1.Patient is not capable of doing an active exercise program

2.Patient has recieved injection therapy for this injury before
3. Patient does not have the intention to return to full sports activity
4.Patient does not want to recieve one of the two therapies
5.Cause of hamstring injury is an extrinsic trauma on posterior thigh
6.Patient has chronic low back pain
7.There are contraindications for MRI:pacemaker, pregnancy, claustrofobia
8.Patient has chronich hamstring complaints (> 2 months)
9.There is a grade 3 lesion (total rupture) on MRI

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-02-2011
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	11-02-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	23-09-2011
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	21-02-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23513
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL34660.098.10
OMON	NL-OMON23513