Dutch Hamstring Injection Therapy study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23513

Source
Nationaal Trial Register

Brief title
Dutch HIT study

Health condition

Acute hamstring injury
Acute hamstringblessure
Autologous Conditioned Plasma (ACP)
Growth factors

Sponsors and support

Primary sponsor: The Hague Medical Centre Antoniushove
University Medical Centre Utrecht
Sports Medical Centre of the Royal Dutch Football Association
KNVB Sportmedisch Centrum
Woudenbergseweg 56
3707 HX Zeist
telnr: 0343 499285/499150
Source(s) of monetary or material Support: Arthrex Medizinische Instrumente GmbH

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Recovery assessed with a sevenpoints Likert scale;

2. Hamstring force, measured with dynamic hand hold meter;

3. Recurrent hamstring lesions;

4. Maximal and mean pain score in rest and during sprinting assessed with the visual analogue scale (VAS);

5. Pain with isometric contraction against resistance assessed with the visual analogue scale (VAS);

6. Length of pain area during palpation;

7. Clinical hamstring tests:

A. Passive straight leg raising;

B. Active knee extension;

C. Active slump test;

D. Taking shoe out sign.

8. Clinical sacroiliacal tests:

A. Stork test;

B. Multi test regime;

C. Gillet test.

9. Hip- and knee range of motion;

10. Functional outcome score (Tegner acivity score, hamstring outcome score);

11. Subjective patient satisfaction: The patient satisfaction will be determined by the patient to ask how satisfied they are with the effect of the treatment in 4 possible categories:

excellent / good / moderate / poor. The groups "excellent" and "good" will be regarded as successful and the groups of "moderate" and "poor" as not successful;

14. Platelet count in whole blood and ACP;

15. Recovery hamstring lesion on MRI at return to sport.

Hamstring muscle injuries on MRI will be classified according to the three graded classification of Hancock (2009):

1. Grade I: Oedema without architectural distortion (indicating a microtear);

2. Grade II: Partial tear;

3. Grade III: A complete tear (excluded in this study).
This (widely used) classification system will be used for analysis of possible differences at baseline and during the final analysis.

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 shown 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 deliberately 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 a non-randomized control group.

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:

Multi centre, double blind, randomized controlled trial comparing two treatment groups.

Study population:

80 patients with an acute hamstring lesion with MRI abnormalities.

Intervention:

Both the intervention group as the control group will perform exercise therapy. The intervention group is treated with ACP injection at maximal 5 days after the injury and the control group will receive placebo injection at the same time interval. A second injection is provided 5-7 days after the first injection. Injections are performed ultrasound guided in the lesion of the hamstring muscle.

Outcome measurements:

Primary: Time to return to full sports activity; either training or match play.

Secondary: Rate of recovery, hamstring force, recurrent hamstring lesions, pain score in rest, during sprinting and during isometric contraction assessed with the visual analogue scale (VAS), length of pain area during palpation, clinical hamstring- and sacroiliacal tests, hip- and knee range of motion, functional outcome, subjective patient satisfaction, prediction of patient and sports physician for time to return to sports, rediction of the patient of the used intervention (ACP or placebo),platelet count in whole blood and ACP, recovery hamstring lesion on MRI.

Follow-up will be performed after 1, 3, 4, 8, 10, 16, 26, 52 weeks and at return to sports.

Study objective

The time to return to sport is shorter in the patient group treated with Autologous Conditioned Plasma (ACP) injections in combination with exercise therapy in comparison with

the patient group treated with saline injections in combination with exercise therapy.

Study design

Follow-up will be performed after 1, 3, 4, 8, 10, 16, 26, 52 weeks and at return to sports.

Follow-up after 3, 4, 8, 10, 16 and 52 weeks will be performed by phone and will not consist a physical examination.

Intervention

In this double-blind randomised controlled trial two patient groups are compared:

1. Intervention group: ACP injections (3 ml in depots of 1 ml) in combination with exercise therapy;

2. Control group: Saline injections in combination with exercise therapy.

Two injections will be given with 5-7 days in between.

Contacts

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Eligibility criteria

Inclusion criteria

1. Clinical diagnosis of an acute hamstring injury, defined as:

A. Anamnestic acute injury;

B. Anamnestic pain in posterior thigh;

C. Localised pain during palpation of hamstring muscle;

D. Localised pain during passive straight leg raising;

E. Increasing pain during isometric contraction.
2. Isolated hamstring lesion on MRI (increased signal of injured muscle on T2 and/or STIR);

3. First injection will be performed maximal 5 days after injury;

4. Informed consent;

5. Age 18-50 years.

Exclusion criteria

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

2. Patient has received 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 chronic hamstring complaints, defined as 13: recurrent pain or tenderness of hamstring muscle during at least 2 months;

9. There is a grade 3 lesion (total rupture) and/or avulsion on MRI.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-02-2011
Enrollment:	80
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	21-02-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37939
Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2643
NTR-old	NTR2771
CCMO	NL34660.098.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37939

Study results

Summary results
N/A