Dutch Hamstring Injection Trial (HIT)* Follow-up

Published: 29-05-2015
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This aim of this study is to evaluate the secondary outcome measures including three to four year re-injury data.

Ethical review	Not approved
Status	Will not start
Health condition type	Muscle disorders
Study type	Observational non invasive

Summary

ID

NL-OMON42636

Source
ToetsingOnline

Brief title
Dutch HIT FU

Condition

- Muscle disorders

Synonym
acute hamstring injury, hamstring rupture

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden
Source(s) of monetary or material Support: Wetenschapsfonds ziekenhuis

Intervention

Keyword: hamstring injury, long term follow-up, PRP

Outcome measures

Primary outcome

Primary outcome return to play has been published previously.

Secondary outcome

Not previously reported secondary outcome scores include re-injury at three to four year, alteration in clinical and MRI parameters, subjective patient satisfaction and the hamstring-outcome score.

Study description

Background summary

Platelet-rich plasma (PRP) injections are used worldwide to treat acute muscle injuries. We examined whether PRP injections would be efficacious in hamstring injuries. The core methods and the primary outcome measure were published in the New England Journal
of Medicine (NEJM) as *Platelet-Rich Plasma Injections in Acute Muscle Injury*. This aim of this study is to evaluate the secondary outcome measures including three to four year reinjury data.

Study objective

This aim of this study is to evaluate the secondary outcome measures including three to four year re-injury data.

Study design

long term (3-4 years) follow-up of a randomized, double-blind, placebocontrolled trial

Study burden and risks

Based on the current literature we expect no significant burden and risks associated with participation and considered as negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Between February 2011 and November 2012 patients were included that fullfilled the following inclusion criteria:
1. Clinical diagnosis of an acute hamstring injury, defined as 12:
- 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. Isolated hamstring lesion on MRI (increased signal of 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 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:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	80
Type:	Anticipated

Ethics review

Not approved

Date:	29-05-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL53115.098.15