Platelet-Rich Plasma Injection in Chronic Tendinopathy

No registrations found.

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

Summary

ID

NL-OMON25992

Source
Nationaal Trial Register

Brief title
PRICT

Health condition

Midportion Achilles tendinopathy, Platelet-Rich Plasma (PRP)

Sponsors and support

Primary sponsor: The study is prepared at the Erasmus Medical Centre Rotterdam and will be performed at the Hague Medical Centre Antoniushove Leidschendam (departement of Sports Medicine)
Source(s) of monetary or material Support: It concerns an investigation from own institution that is sponsored by manufacturer Biomet (Biomet Biologics, Inc.. Biomet Netherlands, Toermalijnring 600, 3316 LC Dordrecht, Tel: 31 78 629 29 29).

Intervention

Outcome measures

Primary outcome

- VISA-A (Victorian Institute of Sport Assessment-Achilles) questionnaire: this is a validated

instrument specifically designed to evaluate the severity of symptoms (pain and function) in patients with Achilles tendinopathy

Secondary outcome

1. Ultrasonographic Tissue Characterization (UTC): The UTC method is primarily designed for evaluating equine tendons, where “real-time” consecutive transverse ultrasound images are stored on a computer. Thereafter, the tendon can be evaluated in 3 "planes of view" and the stability of the ultrasound pattern can be quantified. Using in vitro studies of isolated equine tendons, it was demonstrated that stability of the ultrasound pattern is highly indicative for the (ultra) structural integrity of the tendon tissue. Various histopathological stages (7 tissues) could be discriminated with a high significance. In the Erasmus Medical Centre, a study is already set up to determine the value of UTC during follow-up of patients with Achilles tendinopathy who are performing eccentric exercises. An effective tool for the diagnosis and management of tendon injuries could contribute to the development of new or improved capabilities in the field of early diagnosis, prevention and in particular the therapeutic area.

Measurements made by the UTC that are carried out:

1. Maximum AP diameter

2. Distance of the lesion from insertion

3. Lesion type (I-IV)

4. Percentage intact collagen bundles.

At the very short term, the reference values of UTC will be collected. Therefore, this method may not yet be defined as a validated diagnostic in human tendons.

2. Power Doppler ultrasound (PDU):

using PDU, the thickness of the Achilles tendon and the degree of neovascularisation (Grade 0-4 +) can be determined.

3. 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.

4. Returning to sports level: the patient will be asked whether they are able to return to their sports level. It is a subdivision in 5 groups:

A. No sports

B. No return in sports

C. Returning in sports but not in desired sport

D. Returning in desired sport, but not yet old level

E. Returning to old level in desired sport.

Study description

Background summary

Introduction- Overuse injury of the Achilles tendon is a common entity in athletes and older athletes are at an increased risk. When the exact origin of tendon pain is unclear, the term tendinopathy is preferred. Most accepted treatment at this moment is an eccentric exercise programme, according to the Dutch guidelines. However, a recent systematic review on the effectiveness of eccentric exercises to treat lower extremity tendinoses concluded that it is unclear whether eccentric exercises are more effective than other forms of treatment.

Recent studies described new treatment strategies in tendinopathies, such as the use of platelet-rich plasma (PRP). Platelets can participate actively in tissue repair processes and stimulate the release of several growth factors. Recently, it was found that platelet-rich plasma clot releasate stimulates cell proliferation, collagen deposition, and enhances the gene expression of matrix degrading enzymes and endogenous growth factors by human tendon cells in vitro. The only published clinical cohort study in tendon research reported 93% reduction of pain for PRP-treated patients with chronic elbow tendinosis. Also on short term follow-up, the PRP injection was more beneficial than injection with an anaesthetic agent.

Aim- To monitor the potential clinical improvement of chronic midportion Achilles tendinopathy after injection with PRP and to evaluate the recovery process in time using a new Ultrasonographic method (Ultrasonographic Tissue Characterisation).

Study population-
In total, 54 patients with symptomatic Achilles tendinopathy will be included in the study.

Study design- The study will be a double-blind randomised single-centre clinical trial comparing 2 treatment groups. The researcher, the sports medicine physician and the patients will be blinded to the received therapy.

Therapy- All patients will perform a heavy load eccentric exercise programme, consisting of 180 repetitions daily. The patients will be randomised into 2 treatment groups: ultrasound guided intratendinous saline injection with eccentric exercises and ultrasound guided intratendinous PRP injection with eccentric exercises.

Follow-up- Follow-up (clinically and ultrasonographically) will be at 6, 12, 24 and 52 weeks. At 24 weeks, the researcher will be unblinded after the analysis of the preliminary data. The patients will remain blinded to the therapy until 52 weeks follow-up. At 52 weeks follow-up a second, blinded researcher will evaluate the patients using the primary and secondary outcome measurements.

Outcome measurements- Primary outcome measurement: VISA-A score, a validated instrument to detect the severity of symptoms in patients with Achilles tendinopathy. As secondary outcome measurements subjective patient satisfaction and return to sports will be rated. For the evaluation of tendon repair, Ultrasonographic Tissue Characterization (UTC) and Power Doppler ultrasound (PDU) will be performed. UTC was previously developed in horse tendons and provides quantitative information on tendon fiber alignment and the related ultra-structural integrity of the tendon tissue through a non-invasive approach.

Study objective

The average VISA-A score is higher in the patient group treated with eccentric exercise therapy in combination with a PRP injection in comparison with the group treated with a saline injection in combination with eccentric exercises.

Study design

Follow-up takes place after 6, 12, 24 and 52 weeks.

Intervention

In this double-blind, prospective randomized clinical single-center study two conservative treatments for Achilles tendinopathy are compared:

1. Combination of eccentric exercises and injection of PRP

2. Combination of eccentric exercises and physiological saline injection

Contacts

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Eligibility criteria

Inclusion criteria

1. Clinical diagnosis "chronic midportion Achilles tendinopathy"

2. Age 18-70 years

Exclusion criteria

1. Clinical suspicion of insertional disorders (pain at the site of the insertion of the Achilles tendon on the calcaneum)

2. Clinical suspicion of an Achilles tendon rupture (Thompson test abnormal and palpabel "gap")

3. Clinical suspicion of plantar flexor tenosynovitis (posteromedial pain when the toes are plantar flexed against resistance)

4. Clinical suspicion of n.suralis pathology (sensitive disorder in the area of the sural nerve)

5. Clinical suspicion of peroneal subluxation (visible luxation of the mm. Peroneï spot in combination with localized pain)

6. Suspicion of internal disorders: spondylarthropathy, gout, hyperlipidemia, Rheumatoid

Arthritis and sarcoidosis.

7. Condition that prevents the patients from executing an active exercise programme

8. Patient has already performed eccentric exercises, according to the schedule of Alfredson et al (12 weeks)

9. Patient has already received an injection of PRP for this injury

10. Patient does not wish, for whatever reason, to undergo one of the two treatments

11. Known presence of a pregnancy

12. Condition of the Achilles tendon caused by medications (arising in relation to moment of intake), such as quinolones and statins

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):	28-08-2008
Enrollment:	54
Type:	Actual

Ethics review

Positive opinion

Date:	25-08-2008

Application type: First submission

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
NTR-new	NL1360
NTR-old	NTR1420
Other	NL 22805.098.08 : ABR
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A