Platelet-Rich Plasma Injection in Chronic Tendinopathy

Gepubliceerd: 25-08-2008 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25992

Bron
NTR

Verkorte titel
PRICT

Aandoening

Midportion Achilles tendinopathy, Platelet-Rich Plasma (PRP)

Ondersteuning

Primaire 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)
Overige ondersteuning: 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).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Clinical diagnosis "chronic midportion Achilles tendinopathy"

2. Age 18-70 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	28-08-2008
Aantal proefpersonen:	54
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	25-08-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1360
NTR-old	NTR1420
Ander register	NL 22805.098.08 : ABR
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A