The value of Platelet-Rich Plasma in chronic midportion Achilles tendinopathy: a double-blind randomised clinical trial

Published: 04-07-2008
Last updated: 08-05-2024

To monitor the potential clinical improvement of treatment of tendon injuries with PRP and to evaluate the recovery process in time using the new UTC method.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON31856

Source
ToetsingOnline

Brief title
PRP injection in Achilles tendinopathy

Condition

- Tendon, ligament and cartilage disorders

Synonym
achillodynia, tendon overuse injury

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Biomet

Biologics,Biomet Biologics;Inc.

Intervention

Keyword: Achilles, eccentric exercises, PRP injection, tendinopathy

Outcome measures

Primary outcome

Primary outcome measurement: VISA-A score, a validated instrument to detect the severity of symptoms in patients with Achilles tendinopathy.

Secondary outcome

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 developed, that provides quantitative information on tendon fiber alignment and the related ultra-structural integrity of the tendon tissue through a non-invasive approach.

Study description

Background summary

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 anesthetic agent.

Study objective

To monitor the potential clinical improvement of treatment of tendon injuries with PRP and to evaluate the recovery process in time using the new UTC method.

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.

Intervention

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

Study burden and risks

The intratendinous injections may be painful and a hematoma can arise. In previous studies on the effect of autologous blood injections or injection with PRP on tendon disorders at other locations, it was reported that no tendon ruptures occured. However, we are not sure whether these results could be extrapolated to the Achilles tendon.
The eccentric exercises are frequently painful and it requires discipline. Moreover, there are 4 follow-up moments for the patients after inclusion (with the duration of 45 minutes per appointment).

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

1.Pain on palpation 2-7 cm proximal from the tendon insertion ("midportion")
2.Symptoms > 2 months
3.Age 18-70 years

Exclusion criteria

1.Insertional Achilles tendinopathy
2.Achilles tendon rupture
3.Tenosynovitis of the plantar flexors
4.Sural nerve pathology
5.(sub)luxation mm. Peroneï
6.Suspicion of a systemic disease:spondylarthropathy, gout, hyperlipidemia, Rheumatoid Arthritis en sarcoidosis
7.Inability to perform a heavy load exercise programme
8.Previous performance of heavy load eccentric exercise programme according to Alfredson et al. (12 weeks)
9.Previous injection with PRP for the same injury
10.Unwillingness of the patient to participate in one of the two treatment groups
11.presence of a pregnancy
12.Prescribed drugs with a putative effect on symptoms and tendon healing, for example

quinolone antibiotics

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-08-2008
Enrollment:	54
Type:	Actual

Ethics review

Approved WMO

Date:	04-07-2008
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL22805.098.08