The ATP Study: Autologous platelet-leucocyte rich plasma treatment in achillestendinopathy to speed up healing and shorten the return to activity time.

Published: 17-08-2009
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This study is designed to evaluate the efficacy of autologous P-LRP in the treatment of Achilles tendinopathy, in order to achieve an earlier return to activities.

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

Summary

ID

NL-OMON33326

Source
ToetsingOnline

Brief title
Achillestendinopathy and P-LRP treatment

Condition

- Tendon, ligament and cartilage disorders

Synonym
achilles tendonitis/tendinosis, Achillestendinopathy

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Stichting Feret

Intervention

Keyword: Achillestendinopathy, P-LRP

Outcome measures

Primary outcome

Earlier return to sport and daily-activities, based upon the VISA-A score.

Secondary outcome

Pain assessment, patient satisfaction, recurrence rate and ultrasound control

Study description

Background summary

There is a high prevalence of Achilles tendinopathy in active people and recreational and professional athletes causing significant inactivity. At this moment, there is noconsensus on the best form of conservative treatment, because there is insufficient evidence from randomised controlled trials. The best accepted treatment is a rehabilitation program, based on eccentric training. Autologous P-LRP combines platelet concentrate with thrombin and provides a controlled release of platelet derived growth factors in order to stimulate and increase cellular activity and healing.

Study objective

This study is designed to evaluate the efficacy of autologous P-LRP in the treatment of Achilles tendinopathy, in order to achieve an earlier return to activities.

Study design

A prospective, randomised study

Intervention

Ultrasound guided injection of platelet-leucocyte rich plasma in Achillestendinopathy.

Study burden and risks

Theoretically blood is at risk for bacterial contamination at the moment of drawing blood from the patient to fill the preparation unit. From the preparation process until the application of the P-LRP the whole process is fully automated. Therefore the risk for bacterial contamination is practically eliminated compared to conventional preparation techniques.

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

Clinical diagnosis of Achillestendinopathie (see also page 16 of protocol).
Established diagnosis of maximum 3 months.

Exclusion criteria

Tendonruptures
History of ankle or Achillestendon operation
Other explanations for pain Achillestendon (i.e. arthritis)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-08-2010
Enrollment:	126
Type:	Actual

Ethics review

Approved WMO

Date:	17-08-2009
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL26947.060.09