The PLET-Study: Autologous platelet-leukocyte rich plasma treatment in lateral elbow tendinopathy 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 lateral elbow tendinopathy, in order to achieve an earlier return to activities and fit to play.

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

Summary

ID

NL-OMON33398

Source
ToetsingOnline

Brief title
Lateral elbow tendinopathy and P-LRP treatment

Condition

- Tendon, ligament and cartilage disorders

Synonym
Lateral elbow tendinopathy, tenniselbow

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Lateral elbow tendinopathy, P-LRP, Tenniselbow

Outcome measures

Primary outcome

Earlier return to activities, confirmed by Nirschl-classification and

DASH-scores.

Secondary outcome

Pain assessment, patient satisfaction, recurrence rates and ultrasound control.

Study description

Background summary

Laterale elbow tendinopathy (tenniselbow) is a common soft tissue injury. It causes pain and loss of function and therefore considerable morbidity and financial cost. At this moment there is noconsensus on the best form of treatment and numerous methods and interventions have been used, but high level evidence is lacking. Autologous P-LRP 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 lateral elbow tendinopathy, in order to achieve an earlier return to activities and fit to play.

Study design

A prospective, randomised trial

Intervention

Ultrasound guided injection of platelet-leucocyte rich plasma in lateral elbow tendinopathy.

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 lateral elbow tendinopathy (see also page 16 of protocol).
Established diagnosis of 3 months.

Exclusion criteria

Tendonruptures
History of elbowoperation
Other explanations for pain lateral elbow (i.e. arthrosis)

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	NL27357.060.09