Effect of a Platelet Rich Plasma (PRP) injection on the outcome of chronic lateral epicondylitis. A double blinded randomized controlled clinical trial.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20829

Source
Nationaal Trial Register

Health condition

PRP injection/PRP injectie
Lateral Epicondylitis/ Epicondylitis Lateralis
Tenniselbow/Tenniselleboog
Tendinopathy/Tendinopathie

Sponsors and support

Primary sponsor: Ziekenhuis Gelderse Vallei/RMC Grootklimmendaal
Source(s) of monetary or material Support: Ziekenhuis Gelderse Vallei/RMC Grootklimmendaal

Intervention

Outcome measures

Primary outcome

The Patient Rated Tennis Elbow Evaluation (PRTEE) questionnaire at six months

Secondary outcome

-VAS score

- Ultrasound at six months

- DASH score (including the work and sports/performing arts module)

- Pain-free grip strength and maximum grip strength measured with a dynamometer.

- Three global change indices (GCI) which consist of the quality of the most commonly performed activity (e.g. hammering or writing), the satisfaction of the individual with the received treatment and the amount of compliance of the home based exercises.

Study description

Background summary

Rationale:

Lateral Epicondylitis (LE) is a common problem in the general population. It is responsible for disabilities in daily living, as well as disabilities in work and sports. Unfortunately there isn¡¯t one therapy that improves the outcome on the chronic variant of this disease. Platelet Rich Plasma (PRP) contains an 8-fold increase in platelets compared to whole blood. The platelets contain several growth factors which enhance tissue regeneration and healing. Good results are obtained in in vitro studies with tendons, in vivo studies show conflicting results.
Objective:

The main objective of this study is to examine if a single injection of PRP results in a 15 point reduction on the Patient Rated Tennis Elbow Evaluation (PRTEE) questionnaire at six months compared to an injection with saline in a therapy resistant population with chronic lateral epicondylitis.
Study design:

A double blinded randomized controlled clinical trial
Study population:

Patients presented to the orthopaedics and rehabilitation departments of Hospital Gelderse Vallei with elbow epicondylar pain increasing with pressure and with resisted wrist extension for more than 6 months and resistant to a well structured 5 week rehabilitation program, aged 18 ¨C 70 years with abnormal findings on the ultrasound, suspicious for lateral epicondylitis.

Intervention :

One group receives an injection with three millilitre (ml) Platelet Rich Plasma (PRP) and the other group receives an injection with three ml saline.
Main study parameters/endpoints:

The main study parameter is the difference in improvement expressed in the PRTEE score at six months between the PRP-group and the control group.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

From all patients 27 ml of blood is withdrawn from the cubital vein, half of the patients receives an injection with three ml of PRP which is worked up from their blood. The other half receives a saline injection and their blood is discarded. All patients visit the hospital at four weeks, three months and six months for 30 minutes. During their visit they fill in a questionnaire, which contain the PRTEE, the Visual Analog Scale (VAS), the Disability of Arm Shoulder and Hand (DASH) and three Global Change Indices which evaluate the quality of the most commonly performed activity, the satisfaction of the individual with the received treatment and the amount of compliance of the home based exercises. Furthermore the pain-free grip strength and maximum grip strength will be measured with a dynamometer. At six months an ultrasound will be made, which will be compared to the ultrasound at the time of the injection.

Study objective

A single PRP injection result in a clinical relevant reduction of the complaints at six months, compared to an injection with saline.

Study design

- Time of injection (t=0)

- 1 month

- 3 months

- 6 months

Intervention

One group receives an injection with three millilitre (ml) Platelet Rich Plasma (PRP) and the other group receives an injection with three ml saline.

Contacts

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Eligibility criteria

Inclusion criteria

- patients with elbow epicondylar pain increasing with pressure and with resisted wrist extension or with resisted third finger extension

- duration >6 months

- Resistant to conservative treatment programs

- PRTEE score of ¡Ý 40.

- Aged 18 ¨C 70 years

- Abnormal findings on the ultrasound, suspicious for lateral epicondylitis(Abnormal findings are abnormal echogenicity, calcifications , thickened origo of the extensor tendon, irregular erosive cortex of the lateral epicondyl, neovascularisation and ruptures).

Exclusion criteria

- Previous local injection therapy in the past six months

- Use of NSAIDs

- Pregnancy

- Other diseases with potential influence on the tendinopathy or PRP treatment effect, such as inflammatory arthritis, autoimmune disease, CRPS, fibromyalgia, or signs of posterior interosseous nerve entrapment.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2015
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-12-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40290
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4903
NTR-old	NTR5005
CCMO	NL44980.041.14
OMON	NL-OMON40290

Study results

Summary results
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