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

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20829

Bron
Nationaal Trial Register

Aandoening

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

Ondersteuning

Primaire sponsor: Ziekenhuis Gelderse Vallei/RMC Grootklimmendaal
Overige ondersteuning: Ziekenhuis Gelderse Vallei/RMC Grootklimmendaal

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

- Time of injection (t=0)

- 1 month

- 3 months

- 6 months

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-12-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40290
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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