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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The effectiveness of PRP treatment in patients suffering from chronic lateral epicondylitis is still ambiguous. Therefore we study PRP treatment in a double blind randomized controlled trial in a homogeny patient population with respect to duration...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Administration site reactions
Study type	Interventional

Summary

ID

NL-OMON40290

Source
ToetsingOnline

Brief title
Effect of a PRP injection on chronic lateral epicondylitis.

Condition

- Administration site reactions
- Tendon, ligament and cartilage disorders
- Skin and subcutaneous tissue therapeutic procedures

Synonym
Lateral epicondylitis, Tenniselbow

Research involving

Human

Sponsors and support

Primary sponsor: Ziekenhuisvoorzieningen Gelderse Vallei
Source(s) of monetary or material Support: RMC Groot Klimmendaal

Intervention

Keyword: Lateral Epicondylitis, PRP injection, Tendinopathy, Tenniselbow

Outcome measures

Primary outcome

Primary endpoint is the PRTEE-score at six months. This score is build up out of two parts, a section of five questions about pain and a section of ten questions about functional disabilities. The functional section consists of six questions about specific activities and four questions about usual activities. All questions can be rated from zero to ten. For calculating the total PRTEE score the total of the function section is divided by two and added to the pain section. The PRTEE has proven to be a reliable questionnaire and sensitive to change

Secondary outcome

Secondary endpoints are the VAS score, an ultrasound at six months, DASH score including the work and sports/performing arts module to evaluate the quality of work and leisure time in relation to the complaints of the lateral epicondylitis. Furthermore the pain-free grip strength and maximum grip strength will be measured with a dynamometer. The mean value (kg) of three efforts will be calculated, separated by 20 seconds rest intervals. 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. The GCI are scored using a transitional scale. Complications

and reinterventions will be registered.

Study description

Background summary

Tendinopathy is a common problem in the general population. It may result from acute trauma, but more commonly from overuse. One of the most common tendinopathies for the upper extremity is lateral epicondylitis . The incidence of lateral epicondylitis in the general population is 0.54 percent, which increases to 1.26 percent for the age group of 40 to 50 years and decreases with older age.
Lateral epicondylitis is known to be a self limiting disease, since 80 % of the patients with symptoms of a more than six weeks lasting lateral epicondylitis are much improved or completely recovered within six months and 90% within one year . In this study a six point Likert type scale was used for measuring the improvement. Success rates were calculated from this scale by scoring *much improved* en *completely recovered* as a success. When separating these two outcomes a large difference is seen, with *completely recovered* being far less than *much improved*.
Another study shows that only one third of the patients reports full recovery at one year implicating that many patients keep complaints. Among the factors that predict poor outcome are long duration of elbow complaints and severe pain at presentation and probably history of elbow complaints, involvement of the dominant side, female gender and older age.
For patients with chronic complaints, different treatment options have been proposed. The injection with corticosteroids is still a treatment which is frequently used. However, recent research shows although the short term results are better, the long term results are worse compared to wait and see policy or physiotherapy .
New therapies are being developed, because current therapies are not satisfactory in patients with chronic complaints. One promising new therapy is local injection with Platelet Rich Plasma (PRP). PRP can be derived from centrifuging autologous whole blood. This procedure results in an 8-fold increased platelet plasma concentration . In the *90s the PRP injection was utilized for surgical wound healing. The platelets enhance tissue regeneration and healing . Later on, PRP injections were also used in the treatment of tendinopathies .

Several studies compared a PRP injection with another injection therapy.
Two studies compared the effectiveness of a PRP injection to the effectiveness of autologous blood injection. Only after six weeks there was a statistically significant difference in pain in favour of PRP, which disappeared in the long term20. Both therapies are useful in patients who are resistant to physiotherapy: approximately 70% improved in clinical outcomes. No statistically significant difference was detected between the two therapies. In the study of Creaney et al. the investigators gave 2 injections instead of one, the second one a month after the first one. Furthermore one of the exclusion criteria was having had an injection therapy in the past. The percentage converted to a surgery was twice as high in the autologous blood group compared to the PRP group (20%vs10%).
Wolf et al. found no difference in outcome as for function and pain when injections with PRP, corticosteroids and saline, all with 1 ml lidocaine, were compared . All injection types gave improvement of the tendinopathy. They only included patients with complaints for less than 6 months, which makes it hard to subscribe the improvement to the therapy rather than the natural healing process. Furthermore the mixture of PRP with lidocaine can have a negative influence on the tenocyte proliferation and cell viability of the PRP solution .
Krogh et al. also compared a PRP injection, a glucocorticoid injection and a saline injection . They found no significant pain reduction between the different groups at 3 months, while glucocorticoids had a short term pain-reducing effect at 1 month in contrast to the other therapies. They originally planned the pain PRTEE score at 12 months as their primary endpoint, however due to a high dropout number they decided to use the scores at three months as primary endpoint.
Peerbooms et al. compared a PRP injection to an injection with corticosteroids and found that initially the corticosteroid group did better, however after 8 weeks the PRP group did better up to 1 year . This effect was still visible after 2 years . Because the known poorer outcome at 1 year of the corticosteroid group compared to a wait and see policy, it is difficult to subscribe the significant difference seen in this study to the positive effect of PRP or the negative effect of the corticosteroids.
Kazemi et al compared an autologous blood injection with a corticosteroid injection and saw that the blood injection was more effective in the short term than the corticosteroid injection . This in contrast with the findings that corticosteroids do better in the beginning.
Mishra and colleagues conducted two studies in which they compared an injection with PRP with a injection with bupivacaine. The latest study was conducted with 225 patients. They found a statistically significant drop in painscore of 71.5% after 24 weeks for the PRP group versus 56.1% for the bupivacaine group. No statistically significant difference was found in the PRTEE score, they both improved from baseline to 24 weeks (PRP 54.15-16.17 vs control 57.71 -21.06).
Some conclusions can be drawn from these studies. First of all, none of the studies reported any severe adverse effects. Many studies had serious methodological problems, including the duration of complaints shorter than 6

months, inhomogeneous patient populations, high rates of loss to follow up and an active agent as control. Furthermore, the results do not favour PRP unequivocally compared to other types of injection therapy. The effectiveness of PRP treatment in patients suffering from chronic lateral epicondylitis is still ambiguous. Therefore we study PRP treatment in a double blind randomized controlled trial in a homogeneous patient population with respect to duration of complaints (> 6 months) and insufficient recovery after a 5-weeks multidisciplinary treatment. The following research question is addressed: does a single PRP injection result in a clinical relevant reduction of the complaints at six months, compared to an injection with saline.
By comparing the intervention group with a control group, which receives an inert saline injection, we will be able to subscribe the results to the PRP solution when there is a significant difference. And the patient can be spared from an operation. When there will be no significant difference, this relatively expensive therapy can be replaced by an alternative cheaper therapy. A next interesting question will then be if the same results will be obtained with dryneedling.

Study objective

The effectiveness of PRP treatment in patients suffering from chronic lateral epicondylitis is still ambiguous. Therefore we study PRP treatment in a double blind randomized controlled trial in a homogeny patient population with respect to duration of complaints (> 6 months) and insufficient recovery after a 5-weeks multidisciplinary treatment. The following research question is addressed: does a single PRP injection result in a clinical relevant reduction of the complaints at six months, compared to an injection with saline.

Study design

All outpatients presented to the departments of orthopaedic surgery and rehabilitation medicine with chronic lateral epicondylitis are first offered a rehabilitation program of five weeks, in which they execute a home-based fitness program supported by two visits to the occupational therapist and three visits to the physiotherapist. If necessary, the patients receive a cock-up splint, which they wear during physical activities. Only patients who do not respond sufficiently to the rehabilitation program (PRTEE score *40) and who do meet the inclusion criteria are eligible for this double blinded randomized controlled trial. Since there exists no golden standard therapy, neither evidence based or consensus based, a inert salinw injection was chosen as the optimal control therapy. Patients are only included if they sign the informed consent, implicating that the randomization can proceed.
Participants will be randomly allocated to the experimental group or the control group. The duration of the study will be 6 months from the moment of injection. All visits will be at the department of rehabilitation of hospital Gelderse Vallei and the participants will be guided during these visits by a

physical therapist. The participants who were allocated in the control group will have the opportunity to receive a PRP injection after six months.

Intervention

27 ml of whole blood will be taken from the cubital vein of each patient, three ml of citrate will be added to prevent the blood from clotting. If the patient is randomized to the PRP injection group, the collected blood is centrifuged for 15 minutes at 3200 RPM. The platelet poor plasma is discarded and two ml of PRP will be aspired, after re-suspending the platelets the remaining PRP will be aspired. To match the pH of the tissue in which the PRP is injected, 0.05 ml 8.4 % sodium bicarbonate per ml platelet concentrate is added (GPS III, Biomet, Warsaw Indiana, USA). If the patient is randomized to the control group, the blood will be discarded. The patient will be blindfolded to garante that the patient does not know in which group he is allocated. The radiologist documents the laesion seen on ultrasound, to compare with the ultra sound made after 6 months. The radiologist performs the injection under ultrasound guidance and is not further involved in the follow up.

Study burden and risks

Risks of the injection:
Possible complications: Bleeding, infection, nerve damage, pain and stifness after injection.

Burden:
Venous blood withdrawal and injection in tendon extensor loge of the elbow (90 minutes).
3 visits at 1, 3 and 6 months. During these visits, which will take 30 minutes of their time, the participant fills in a questionnaire and gripstrength will be measured. At six months an ultrasound will be made, which takes another 30 minutes.
Furthermore some do's and dont's around injection time and before the visits to our hospital. They have to perform their exercises, they are'nyt aloud to take NSAID before and after the injection and they can't take a painkiller the two days prior to the visit to our hospital.

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

- Elbow epicondylar pain increasing with pressure and with resisted wrist extension or with resisted third finger extension for more than 6 months and resistant to conservative treatment programs
- Age range 18 * 70 years
- Proved lateral epicondylitis by ultrasound
- Insufficient recovery (PRTEE-score * 40) after an integrated multidisciplinary rehabilitation program

Exclusion criteria

- Previous local injection therapy in the past six months
- Other disease with potential influence on the tendinopathy or PRP treatment effect, such as inflammatory arthritis, autoimmune disease, CRPS or signs of posterior interosseous nerve entrapment
- NSAID use
- Pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Date:	23-12-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20829
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL44980.041.14
OMON	NL-OMON20829