The value of Platelet-Rich Plasma injections in the treatment of the jumper's knee: a double-blind randomised trial

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There is a double study objective:- First the effects of a PRP-injection in the treatment of the jumper's knee in comparison with the effects of a placebo injection - Second the effects of a PRP-injection in comparison with the effects of an...

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

Summary

ID

NL-OMON37132

Source
ToetsingOnline

Brief title
PRP for the jumper's knee

Condition

- Tendon, ligament and cartilage disorders

Synonym
jumper's knee and apexitis

Research involving
Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,Biomet

Intervention

Keyword: autologous blood, jumper's knee, PRP, tendinopathy

Outcome measures

Primary outcome

Primary outcome measure will be VISA-P score. This is a valid scoring system to assess jumper's knee, 100 points maximum, meaning normal functioning knee and 0 points minimum.

Secondary outcome

Secondary outcome measures will be VAS score, return to sports (extent and level), degree of ultrasound pathology and costs.

Study description

Background summary

The jumper's knee is a degenerative condition at the insertion of the patellar tendon at the distal patellar pole. Etiologic factors include aging and mechanic load. The condition thus affects mostly sportsmen. The prevalence among sportsmen is about 14% and an additional 8% had symptoms in the past. Among elite volleyball players the prevalence is 40-50%. The most frequent applied therapy is eccentric training. However, a significant part of the patients keep having symptoms. Extracorporal shockwave therapy, local applied glyceryl trinitrate and sclerosant injections have only showed an average effect. In recent days progress is achieved in the treatment of tendinopathies. Studies were published about the effects of *dry needling*, intratendinous autologous blood injections and intratendinous *platelet-rich plasma*(PRP) injections. However, no studies were published regarding the effects of intratendinous autologous blood injections in comparison with the effects of PRP-injections, nor regarding the effects of intratendinous PRP-injections in the treatment of the jumper's knee.

Study objective

There is a double study objective:
- First the effects of a PRP-injection in the treatment of the jumper's knee in comparison with the effects of a placebo injection
- Second the effects of a PRP-injection in comparison with the effects of an autologous blood injection

Previous studies showed that autologous blood injections in the treatment of the jumper's knee resulted in a decrease of symptoms. Study population will be divided into three groups.

Study design

Sports physicians, general practitioners, physiotherapists and orthopedic surgeons in the region of Utrecht/Amersfoort will receive an information paper about this study, including the request to refer patients matching the inclusion criteria to the study location, sports medicine department, Meander MC, in Baarn.
Inclusion criteria:
- pain at the inferior pole of the patella for 3 months
- age 18-55 year
- tendinosis or thickening compared with the contralateral side of > 3 mm, detected with ultrasonography or MRI
- already undergone eccentric training for 6 weeks following a standardised protocol

Exclusion criteria:
- pregnancy
- injection in the patellar tendon in the last 3 months, irrespective of the applied substance
- operations on the patellar tendon in the past
- calcifications in the proximal patellar tendon
- at examination indications for intraarticular pathology or patellofemoral pain syndrome
- chronic NSAID use in the past 3 months

The intake will include physical examination, assessment of the VISA-P score using a questionnaire and the VAS score and ultrasonography of both patellar tendons to show an area of tendinosis. Also the diameter of the proximal tendon and the number of neovessels will be determined. Then patients will be randomised into three matching groups (group 1 placebo injection, group 2 autologous blood injection, group 3 PRP-injection). 27 cc of blood will be collected from all patients from the antecubital fossa to obtain 3 cc of PRP, using the mini GPS II system of Biomet. Preparation time will be 15 minutes. Then local anaesthesia will be applied using lidocaine. After this the tendon will be 'dry-needled' 5 times under ultrasound guidance and, depending on randomisation, the right fluid will be injected. All this will occur double-blind, because the syringe will be blinded and the intervention will be

executed by a physician who is not involved in the follow-up.

Following the injection the first two weeks activities more strenuous than daily life (e.g. jumping and running) are forbidden. Then a standardised physiotherapy protocol under the supervision of a physiotherapist is conducted to aid rehabilitation. After three months a second ultrasonography will assess tendinosis, thickness of the tendon and number of neovessels. Follow-up including VISA-P score, VAS score and physical examination will take place after 6, 12, 26 and 52 weeks. Primary outcome measure will be VISA-P score. This is a valid scoring system to assess jumper's knee, 100 points maximum, meaning normal functioning knee and 0 points minimum. Secondary outcome measures will be VAS score, return to sports (extent and level), degree of ultrasound pathology and costs.

Intervention

27 cc of blood will be collected from all patients from the antecubital fossa to obtain 3 cc of PRP, using the mini GPS II system of Biomet. Preparation time will be 15 minutes. Then local anaesthesia will be applied using lidocaine. After this the tendon will be 'dry-needled' 5 times under ultrasound guidance and, depending on randomisation, the right fluid will be injected.

Study burden and risks

Patients are asked to visit the sports medicine department 5 times. On two or three occasions ultrasonography of the patellar tendon will take place (depending on what kind of imaging already took place). 27 cc of blood will be collected. All patients receive an injection at the site of the tendinosis. There is a small risk of infection, as with every injection, but no infections have been reported in earlier studies. Except for a short (maximum 1 week) aggrevation of the pain, no other risks or side effects have been reported in earlier studies.

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

- pain at the inferior pole of the patella for 3 months
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Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2009
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	02-02-2009
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-01-2011
Application type:	Amendment
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	NL23993.100.08