# Clinical Effectiveness and Feasibility of Platelet Rich Plasma Injection in Patients with Chronic Patellar Tendinopathy

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Aim of this study is to determine the safety and feasibility and to gain a first insight into the effects of the PRP treatment protocol on pain, symptoms and function, in athletes with chronic patellar tendinopathy.

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

## Summary

### ID

NL-OMON34982

**Source**
ToetsingOnline

**Brief title**
TOPPRIK

### Condition

- Tendon, ligament and cartilage disorders

**Synonym**
Jumper's Knee, patellar tendinopathy

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Jumper's Knee, patellar tendinopathy, Platelet Rich Plasma (PRP)

## Outcome measures

### Primary outcome

Part I

Side effects and adverse reactions/events. Experiences of the patients.

Part II

Self reported VISA-P score

The Dutch VISA-P score is a simple, reliable instrument for measuring the severity of patellar tendinopathy and is sensitive to small changes in symptoms. It was specifically designed for patellar tendinopathy, rating pain, symptoms, simple test of function and the ability to play sports. Six of the eight questions are scored on a VAS from 0 to 10 points, with 10 representing optimal health. The maximum VISA-P score for an asymptomatic athlete is 100 points. The VISA-P score will be obtained for both legs separately.

### Secondary outcome

• Answer to the question: *How is your knee now as compared with before treatment?*, by marking an 11-point visual numerical scale

• Rate the pain on a Visual Analogue Scale (VAS) in which 0 represents no pain, and 100 maximal pain:

o during activities of daily living (ADL),

o during sports,

o during a functional test: the single leg decline squat (SLDS);

o during a jump test: 3 jumps on both legs, 3 jumps on the best leg, 3 jumps on the affected leg.

o during a triple hop test

• Rate overall treatment satisfaction, with use of a 4-grade scale

• Answer the question if they would recommend PRP injection treatment to family or friends; *yes* or *no*.

• Ultrasound characteristics (hypo-echogenity, diameter, calcifications, neovascularisation)

• Side effects and adverse reactions/events

• Height and distance of the jump tests.

• Number of platelets of the prepared PRP

## Study description

**Background summary**

Despite its frequency and impact on athletic careers and in spite of decades of research, management of patellar tendinopathy remains frustrating and unpredictable for both athletes and clinicians. PRP appears to be a promising treatment method in patients with chronic patellar tendinopathy, referred to a sports medicine department after other conservative treatments had failed. PRP treatment for chronic patellar tendinopathy is used in several medical centers in The Netherlands and abroad. However, research on this treatment for patellar tendinopathy is scarce and methodologically poor. Therefore it is important to investigate the clinical effectiveness and feasibility of a non commercial prepared PRP treatment with a better monitoring of the patients.

**Study objective**

Aim of this study is to determine the safety and feasibility and to gain a first insight into the effects of the PRP treatment protocol on pain, symptoms

and function, in athletes with chronic patellar tendinopathy.

## Study design

This study consists of two parts. In the first part the safety and feasibility of the PRP treatment protocol of the Center for Sports Medicine UMCG will be investigated in a small number of patients (n=5). The findings of the first part will be reported to the METc. When no serious adverse events have occurred, another 15 patients will be treated and monitored to gain a first insight into the clinical effectiveness of the PRP treatment protocol, which facilitates a power calculation for a future randomized controlled trial.
This prospective pilot cohort study uses one treatment group with repeated measures. Subjects who visit the Center for Sports Medicine, who are diagnosed having a chronic patellar tendinopathy by one of the sports medicine physicians and who are willing to participate in the study, will receive the PRP treatment program. This includes one PRP injection followed by a 12 week rehabilitation and exercise program supervised by a physical therapist.
In the first part, five patients will receive a PRP injection. The feasibility and safety of the injection will be closely monitored. The patients will be instructed to immediately contact the Center for Sports Medicine UMCG in case of fever, unexpected increase of pain, other side effects or signs of an infection. Furthermore the diaries of these patients will be closely evaluated. After 4 weeks, both patients* and our experiences will be evaluated and reported to the METc. After the first part the treatment protocol will be refined when necessary. In case no serious adverse events have occurred after 4 weeks, another 15 patients will be treated to gain a first insight into the effect of this treatment protocol. Additionally, a possible learning curve will be evened out.
In the second part, a baseline measurement will take place on the day of injection, followed by measurements after physical therapy or regular appointments with the sports medicine physician. These measurements will be half way the treatment protocol (6 weeks from baseline), at the end of the treatment protocol (12 weeks from baseline) and 4 and 14 weeks after the end of the treatment protocol (16 and 26 weeks from baseline) (see timeline). During these measurements, outcome parameters will be assessed by the investigator. At these evaluation moments subjects will complete the VISA questionnaire and perform functional loading (decline squat, triple hop test, jump test). This questionnaire and these tests are regularly used by the physical therapist or sports medicine physician, although now systematically recorded by the investigator. The patients will also rate their satisfaction with the treatment. Treatment and functional tests will take place at the Center for Sports Medicine UMCG.

## Intervention

PRP treatmen (PRP injection in patella tendon followed by a physical therapy

program)

**Study burden and risks**

PRP treatment seems to be an effective treatment for chronic patellar tendinopathy so this can be of great benefit to the subjects receiving this treatment. PRP treatments are already performed worldwide and to our knowledge no copmlications or severe adverse events are reported. The risks for the patients is low. The burden because of the research is low as well, all questionnaires and physical tests occur after regular consultations with a physiotherapist or sports medicine physician. Furthermore, it will take only approximately 5 minutes per week to fill in the diary.

# 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

• History of knee pain in the proximal section of the patellar tendon or its patellar insertion (pointed out in a anatomical drawing of the knee) in connection with training and competition
• Symptoms for over twelve months (current symptoms for at least three months)
• Age 18-40 years old
• Palpation tenderness to the corresponding painful area
• VISA score < 80
• Ultrasound characteristics showing hypoechoic zones in the corresponding area
• Recalcitrant to conservative treatment (at least eccentric training)

### Exclusion criteria

• acute knee or patellar tendon injuries
• chronic joint diseases
• signs or symptoms of other coexisting knee pathology
• pregnancy
• Bleeding disorders and haematological disaeses
• Malignancy
• knee surgery
• injection of any kind in the patellar tendon in the last preceding three months
• use of NSAID*S in the last 5 days before or first 6 weeks after injection or daily use of drugs with a putative effect on patellar tendinopathy in the last year (e.g. non-steroid anti-inflammatory drugs, fluorchinolones)
• actual use of anticoagulants

## Study design

### Design

**Study type:** Interventional

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 26-03-2010 |

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| Enrollment: | 20 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 01-03-2010 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

## 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 | NL31079.042.09 |