

# A trial evaluating the efficacy of cell therapy based on autologous platelet-rich plasma (PRP) for the treatment of Achilles and Patellar tendinopathies

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<b>Registration date</b> 11/11/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/11/2013	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Achilles tendinopathy (a condition that causes pain, swelling, stiffness and weakness of the Achilles tendon that joins the heel bone to the calf muscles) and patellar tendinopathy (an injury that affects the tendon connecting your kneecap to your shinbone) are burdensome conditions of the ankle and knee with loss of function of the Achilles and patellar tendons. These conditions are common and often difficult to treat with prolonged recovery times and could restrict the activity or even force elite athletes to early retirement. Lately, cell-based treatments have attracted attention and amongst them, platelet-rich plasma (PRP) is gaining acceptance as a new treatment. Although several studies have reported positive results, a clear advantage of the PRP injections has not been demonstrated and furthermore most of the studies have combined PRP with other treatments such as physiotherapy. Moreover, the current findings are not sufficient to confirm whether the real positive effect of this treatment are the platelets themselves with the various growth factors that it contains. The aim of this study is to evaluate the effectiveness of platelet-rich plasma (PRP) injections compared with platelet-poor plasma (PPP) injections as an independent therapeutic strategy for the treatment of Achilles and patellar tendinopathies.

### Who can participate?

The study aims to recruit 128 patients (64 with achilles tendinopathy and 64 with patellar tendinopathy) aged between 18 and 60 years old with exercise-associated pain for more than 6 weeks.

### What does the study involve?

Patients are randomly allocated to one of two groups. The first group will receive PRP and the second group will receive PPP. Patients will receive PRP or PPP as two injections with an interval of 4 weeks under ultrasound guidance in the affected tendon. Follow-up visits for a short questionnaire and possibly an ultrasound evaluation will be carried out at 4 weeks, 2 months and 4 months. An additional questionnaire-assisted evaluation is planned at 12 months.

What are the possible benefits and risks of participating?

The benefit for the subjects is a decrease in their pain level and therefore an improvement of the function of their ankle or knee. The risks include discomfort or pain in the region of treatment administration for some days, development of infection following the injection and finally the possibility that the treatment will result in no improvement.

Where is the study run from?

The study will take place in the Sports Medicine Clinic of the Department of Musculoskeletal Medicine (DAL) of the University Hospital Complex of Vaud, Switzerland.

When is the study starting and how long is it expected to run for?

The study started in October 2013 and is expected to end in late 2014.

Who is funding the study?

This study is funded by the Research Foundation of the Orthopedics University Hospital of Lausanne, Switzerland.

Who is the main contact?

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## Contact information

### Type(s)

Scientific

### Contact name

Dr Ilias Petrou

### Contact details

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## Additional identifiers

### Protocol serial number

UTR-CPR-DAL / 20130816

## Study information

### Scientific Title

Double-blind randomized controlled trial to evaluate the efficacy of cell therapy based on autologous platelet-rich plasma (PRP) for the treatment of Achilles and patellar tendinopathies

**Acronym**

PRP-Tendinopathy

**Study objectives**

Our hypothesis is that the procedure with the presence of more platelets and their growth factors (PRP > platelet-poor plasma [PPP]) should produce better clinical outcomes and could be used as an independent therapeutic strategy for the treatment of Achilles and patellar tendinopathies.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Regional (VD) Ethical Committee of Human Health Research; 16/08/2013; ref: 217/13

**Study design**

Randomised controlled trial with blinded participants and investigators using two-group repeated measures

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Achilles tendinopathy, patellar tendinopathy

**Interventions**

The subjects will be randomized to one of two groups. The first group will receive PRP and the second PPP as a therapeutic agent in a double-blinded methodology. Each subject will receive two ultrasound-guided injections with an interval of 4 weeks.

Platelet-rich plasma (PRP): we will use the current Standard Operating Procedure of the Centre Hospitalier Universitaire Vaudois (CHUV). About 18 ml of full blood will undergo a double centrifugation technique (2 x 15 minutes at 280 g) and produce approximately 3 ml of PRP. No activator will be used prior to the injection. The PRP will be injected blinded and under ultrasonographic control.

Platelet-poor plasma (PPP): we will use the current Standard Operating Procedure of the CHUV. About 18 ml of full blood will undergo a double centrifugation technique (2 x 15 minutes at 280 g) and produce approximately 3 ml of PPP. No activator will be used prior to the injection. The PPP will be injected blinded and under ultrasonographic control.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

1. The Victorian Institute of Sport Assessment Questionnaire (VISA-A for Achilles tendinopathy and VISA-P for patellar tendinopathy, to assess the severity of symptoms in patients with tendinopathy)
2. For the Achilles tendinopathy: Foot and Ankle Ability Measure (FAAM) (to assess the symptoms and function of the ankle and foot)
3. Visual analogue scale (VAS): The VAS-pain and will be measured with a scaled line from 0 to 10 cm. The subject will indicate on the scale the level of their pain during the last week before the scheduled visit.
4. Ultrasonographic imaging done prior to the first injection and after the treatment
5. Demographic variables (name, address, age, gender, telephone number)
6. Medical history (i.e., lower limb injuries and previous medical treatments)
7. Clinical examination of the affected region
8. Sports participation: type and level of sport and mean hours of sports participation

### **Key secondary outcome(s)**

Rapport of the overall satisfaction of the procedure as well as the impression of the response to the treatment. These parameters will be measured with a scaled line from 0 to 10 cm. These outcomes will be measured at baseline, 4 weeks, 2 months, 4 months and 12 months.

### **Completion date**

30/12/2014

## **Eligibility**

### **Key inclusion criteria**

1. History (> 6 weeks) of exercise-associated pain along the proximal insertion of the patellar tendon or the Achilles tendon
2. Being at least 18 and no more than 60 years old, either sex
3. Radiologic confirmation of the tendinopathy (MRI or ultrasound)
4. Patient who has signed an informed consent

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. Absence of informed consent/participation in some other clinical trial
2. Presence of inflammatory/rheumatoid or systemic conditions
3. Presence or history of complications of important lower limb injuries

4. Presence of acute affections of the lower limb (i.e., infection, tendon rupture)
5. Patients requiring non-steroidal anti-inflammatory drug (NSAID) treatment for other type of affections
6. Patients undergoing medical treatment that could inhibit tendinopathies (i.e., fluoroquinolones)

**Date of first enrolment**

08/10/2013

**Date of final enrolment**

30/12/2014

## Locations

**Countries of recruitment**

Switzerland

**Study participating centre****Regenerative Therapy Unit (UTR)**

Lausanne

Switzerland

1066

## Sponsor information

**Organisation**

University Hospital Complex of Vaud (Centre Hospitalier Universitaire Vaudois [CHUV])  
(Switzerland)

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

Research Foundation of the Orthopedics University Hospital of Lausanne (Switzerland)

## Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration