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

Submission date
04/10/2013

Recruitment status
No longer recruiting

Registration date
11/11/2013

Overall study status
Completed

Last Edited
11/11/2013

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
Professor Wassim Raffoul , Wassim.Raffoul@chuv.ch
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
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.

Overall study start date
08/10/2013

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
A total of 128 patients (64 with Achilles tendinopathy and 64 with patellar tendinopathy)

Key exclusion criteria
1. Absence of informed consent/participation in some other clinical trial
2. Presence of inflammatoryrheumatoid 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)

Sponsor details
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Research organisation

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration