

A trial comparing platelet-rich plasma, autologous blood and dry needling for chronic patellar tendinopathy

Submission date 01/02/2013	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 19/07/2013	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 23/01/2019	Condition category Musculoskeletal Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Patellar tendinopathy is a troublesome condition that affects the knee joints with loss of function of the patellar tendon (a tissue that connects muscle to the bone). It is a common and often never-ending problem among athletes and can severely limit or even end an athletic career. With the recent interest in injection treatments and the fact that several studies reported positive results for single procedure, we think it would be of much interest to compare three of the most used procedures for this condition. The aim of this study is to compare three injection treatments for chronic patellar tendinopathy: dry needling, dry needling plus autologous blood and dry needling plus platelet-rich plasma.

Who can participate?

The study aims to recruit 111 patients aged 18 and over with exercise-associated pain for more than 3 months.

What does the study involve?

Patients are randomly allocated to one of three groups. All groups receive 20 needle passes under ultrasound guidance in the tendon and receive either an injection of 5cc of blood, 5cc of platelet concentrate or nothing. Follow-up visits for a short questionnaire and ultrasound scan will be carried out at 6 weeks, 3, 6 and 12 months.

What are the possible benefits and risks of participating?

The benefit for the subject is an improvement in their pain and thereby better function of the knee. The risks include pain during the procedure lasting for a few days, a very small risk of infection following the injection and there is a risk that they don't see any improvement with the treatment.

Where is the study run from?

The study will take place in a private sports medicine clinic, Centre Chiromedic, 1545 de l'avenir, suite 300, Laval, province of Quebec, Canada, H7S 2N5.

When is the study starting and how long is it expected to run for?
The study started in May 2012 and is expected to end in May 2014.

Who is funding the study?
This study is funded by Association Quebecoise des medecins du sport (France) and Arthrex Inc. (USA).

Who is the main contact?
Dr Francis Fontaine
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Study information

Scientific Title
Double-blind randomized controlled trial comparing platelet-rich plasma, autologous blood and dry needling for chronic patellar tendinopathy

Study objectives
Our hypothesis is that the procedure with more growth factors (PRP > autologous blood > dry needling) should produce better outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scientific and Ethical committee on Research of the Health and Social Services Center of Laval (Quebec), approved may 15th, 2012

Primary study design
Interventional

Study design

Randomised controlled trial with blinded participants and outcome assessors, using a three-group repeated measures

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Patellar tendinopathy

Interventions

Dry needling: will be injected through one skin portal with a 22-gauge needle and be anesthetized with a 1:1 mixture of 2% lidocaine and bupivacaine 0,5%. We will then proceed within the abnormal tendon to perform approximately 20 needle passes, using real-time ultrasound imaging for guidance. During the procedure, no lidocaine:bupivacaine will be injected inside the tendon. The syringe will be taped so the subject will not be able to see the colour of the injected product.

Autologous blood subject: the same protocol will be used but 5 ml of blood will be injected while doing the 20 needle passes.

Platelet-Rich Plasma (PRP): we will use the Arthrex kit. The 10 cc of blood will be centrifuged for 5 minutes at 1500 rpm and produce approximately 5 cc of PRP. No activator will be used prior to the injection. The PRP will be injected while doing the 20 needle passes.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

All the subjects will complete a baseline evaluation including:

1. An ultrasound assessment (based on the sonographic features used by Ryan (28). We will compare: tendon thickness, area of hypoechoic region in mm in three axes, severity of hypoechoic area according to a 0-3 ordinal scale, presence of intratendinous tear, mean length of intratendinous tear, presence of intratendinous calcification and finally the extent of neovascularity with colour flow Doppler. Those features will be recorded at each visit.),
2. Two different visual analogue scales (VAS): The VAS-pain and VAS-function will be measured with a scaled line from 0 to 100 mm. The subject will indicate on the scale the level of their pain and functional capacity of their knee during the last week.
3. The Victorian Institute of Sport Assessment Questionnaire (VISA-P, to assess the severity of symptoms in athletes with patellar tendinopathy. Currently, it is the only specific scale for patellar tendinopathy).

The baseline evaluation will also include question about:

1. Demographic variables (name, address, age, gender, and e-mail address)
2. Sports participation: type and level of sport and mean hours of sports participation and sport history)
3. Medical history (knee injuries and previous medical treatment)

Key secondary outcome(s)

Follow-up measurements:

1. VISA-P (to assess the severity of symptoms in athletes with patellar tendinopathy. Currently, it is the only specific scale for patellar tendinopathy),
2. VAS: The VAS-pain and VAS-function will be measured with a scaled line from 0 to 100 mm. The subject will indicate on the scale the level of their pain and functional capacity of their knee during the last week.
3. Ultrasound assessments (based on the sonographic features used by Ryan). We will compare: tendon thickness, area of hypoechoic region in mm in three axes, severity of hypoechoic area according to a 0-3 ordinal scale, presence of intratendinous tear, mean length of intratendinous tear, presence of intratendinous calcification and finally the extent of neovascularity with colour flow Doppler. Those features will be recorded at each visit.)

Measurements will be carried out at 1, 3, 6 and 12 months. Side effects and adverse reactions /events and the rate of overall treatment satisfaction will also be recorded.

Completion date

31/01/2021

Eligibility**Key inclusion criteria**

1. History (> 3 mo) of exercise-associated pain along the proximal insertion of the patellar tendon or pain or tenderness on palpation at this site or pain during provocative tests of the knee extensors
2. And having one of the following ultrasound finding:
 - 2.1. Hypoechoic regions
 - 2.2. Intratendinous tears
 - 2.3. Neovascularisation
3. Being at least 18 years old, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Key exclusion criteria

1. Bleeding disorders (hemophilia)
2. Taking anticoagulants (except aspirin)
3. Severe anemia

4. Cancer or metastases
5. Pregnant or breastfeeding women
6. Presence of infection at the time of evaluation
7. History of knee surgery
8. Inflammatory arthritis affecting the knee
9. Corticosteroid injections within 30 days preceding the study

Date of first enrolment

05/06/2012

Date of final enrolment

31/01/2020

Locations

Countries of recruitment

Canada

Study participating centre

300-1545, boul. de l'Avenir

Laval

Canada

H7S 2N5

Sponsor information

Organisation

Arthrex Inc. (USA)

ROR

<https://ror.org/01vd19x80>

Funder(s)

Funder type

Industry

Funder Name

Arthrex Inc.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes