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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

Registration date
19/07/2013

Overall study status
Completed

Last Edited
23/01/2019

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
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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Study website
http://genouducoureur.com/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
http://www.prpmedic.ca/fr/genou-coureur

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 centrifugedfor 5 minutes at 1500 rpm and produce approximately 5 cc of PRP. No activator will be use prior to the injection. The PRP will be injected while doing the 20 needle passes.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

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)

Secondary outcome measures
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.

Overall study start date
05/06/2012

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
111

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
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Sponsor information

Organisation
Arthrex Inc. (USA)

Sponsor details
Arthrex, Inc.Corporate Headquarters
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Sponsor type
Industry

Website
http://www.arthrex.com/

ROR
https://ror.org/01vd19x80

Funder(s)

Funder type
Industry

Funder Name
Arthrex Inc.

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