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Platelet-rich plasma (PRP) for jumpers knee

Submission date
26/01/2014

Recruitment status
No longer recruiting

Registration date
24/09/2014

Overall study status
Completed

Last Edited
09/10/2015

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
Jumpers knee (patellar tendinopathy) is an inflammation or injury of the tendon that joins the kneecap (patella) to the shin bone (tibia). This tendon is called the patellar tendon. It is an overuse injury which happens when repeated movements cause damage to the tissues to a certain part of the body. Constant jumping, landing and changing direction can cause such damage to the patella tendon. Jumpers knee is therefore often seen in people who play professional or recreational sports . The condition has a huge impact on whether the sufferer can play their sport or indeed their usual daily activities. Treatment usually involves eccentric training, a number of exercises that are designed to strengthen the knee, but the results of this treatment is not satisfactory for a significant number of jumper knee patients. Other treatments for the condition include rest, anti-inflammatory medication, extracorporeal shockwave therapy and surgery. However, no single treatment has proven to result in a consistent, near complete recovery in all patients. In recent years, many studies have been published on the effects of dry needling (a form of acupuncture), autologous blood injection and platelet-rich plasma (PRP) injections. All of these treatments have had positive results. The latter two treatments work by releasing growth factors and other substances into the knee that boost the healing process in chronic injury. However, autologous blood injections involve injecting a patients own blood from another part of the body into the joint while PRP injections works by injecting just the plasma component of the blood. We want to compare how successful the PRP injection is at treating jumpers knee compared to the autologous blood injection and a saline injection.

Who can participate?
Participants diagnosed as having a jumpers knee, aged between 18-55 years old and have already been treated with eccentric training for 6 weeks.

What does the study involve?
Participants are randomly allocated into one of three groups. Those in group 1 are treated with a PRP injection. Those in group 2 are treated with a autologous blood injection . Those in group 3 are treated with a saline injection. All participants are asked to fill in a questionnaire about how well their knee works and how painful it is before treatment starts and then at 6, 12, 26 and 52 weeks after treatment.

What are the possible benefits and risks of participating?
Based on previous studies, a reduction of pain and improvement in function can be expected

from any of the three injection treatments. A slight increase in pain is possible the first few days after injection. As with any injection, a very small risk of inflammation exists.

Where is the study run from?
Participants are recruited at two medical centers in The Netherlands. Meander Medical Center in Baarn and University Medical Center in Groningen.

When is study starting and how long is it expected to run for?
March 2009 to December 2015.

Who is funding the study?
Meander Medical Center, Baarn (Netherlands)
University Medical Center, Groningen (Netherlands)
Biomet Europe B.V. (Netherlands)

Who is the main contact?
Mathijs van Ark
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ABR nr: NL23993.100.08

Study information

Scientific Title
The value of platelet-rich plasma injections in the treatment of the jumpers knee: a double blind randomized trial

Study objectives
Platelet-rich plasma injection treatment results in more improvement in pain and function of a jumpers knee patient than an autologous blood or saline injection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee Examination Scientific Research of Meander Medical Center, The Netherland (The Commissie Toetsing Wetenschappelijk Onderzoek [CTWO]), 06/03/2009 ref.:(v.09.028/R.08.30). Medical Ethics Committee of University Medical Center Groningen, 24/01/2011, ref.: (METc nr 2010.193) - Approval for multi center recruitment for this study

Study design
Double-Blind Randomized Controlled Trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Patellar tendinopathy (jumper's knee)

Interventions
PRP, autologous blood or saline injection

Blood (54cc) will be extracted from the elbow vein in every patient, because this is necessary to obtain 6cc PRP. The liquid to be injected will be placed in a 10ml blinded syringe by someone else than the treating physician and radiologist. The location of penetration will be anesthetized with Lidocaine. Subsequently, the tendon will be dry-
needled five times under ultrasound guidance. Depending on the injection treatment, the correct liquid will be injected under ultrasound guidance (injections described below). This will occur double-blind, the syringe will be blinded to the treating physician and radiologist.

The researcher who will analyse the data will be blinded as well. The first two weeks after injection the patient should not take part in any (sport) activities with higher load than normal daily life activities. After two weeks, the load will be increased during a standardized supervised

physiotherapy protocol. This protocol will take approximately 12 weeks. The first month after injection, patients are not allowed to use NSAIDs. Final follow-up will be one year after injection treatment.

Platelet-Rich Plasma injection (PRP)
The mini GPS II kit from the company Biomet B.V. will be used to prepare 6ml of PRP and placed in a blinded syringe for injection.

Autologous blood
A part (6ml) of the extracted blood will be placed in a blinded syringe for injection.

Saline
NaCl (6ml) will be placed in a blinded syringe for injection.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
VISA-P a validated questionnaire for patellar tendinopathy which assesses pain and function of the knee (100 = maximal score, indicating a normal functional knee, 0 = minimal score).
This will be assessed at baseline, 6, 12, 26 and 52 weeks after injection treatment.

Secondary outcome measures
1. Ultrasound abnormalities (tendinosis zone, thickness of tendon and degree of neovascularisation) at baseline and 12 weeks after injection
2. Pain, measured using Visual Analogue Scale (VAS) score (0 = no pain, 10 = unbearable pain)
3. Costs of the treatments
4. Return to sport (level and duration)

Overall study start date
06/03/2009

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Jumpers knee patients aged 18-55
2. Pain at the inferior pole of the patella for more than 3 months
3. Tendinosis or thickening compared to the contralateral side of > 3mm, detected with ultrasonography or MRI
4. Already undergone eccentric training for 6 weeks following a standardized protocol

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
90 Divided over 3 groups

Key exclusion criteria
1. Pregnancy
2. Injection in the patellar tendon in the last 3 months, irrespective of the applied substance
3. Operation on the patellar tendon in the past
4. At examination indications for intra articular pathology or patellofemoral pain syndrome
5. Chronic NSAID use in the last 3 months

Date of first enrolment
06/03/2009

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
P.O. Box 30.001
Groningen
Netherlands
9700 RB

Sponsor information

Organisation
Biomet Europe B.V. (Netherlands)

Sponsor details

Toermalijnring 600
Dordrecht
Netherlands
3316 LC

Sponsor type
Industry

ROR
https://ror.org/034k8cv93

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Biomet Europe B.V. - Supplied the PRP preparation kits free of cost and funding for 0.1 FTE junior researcher for 1 year (euro 5000) (Netherlands)

Funder Name
Meander Medical Center, Baarn (Netherlands)

Funder Name
University Medical Center, Groningen (Netherlands)

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