ISRCTN68341698 https://doi.org/10.1186/ISRCTN68341698

Effectiveness of platelet-rich plasma therapy for painful conditions

Submission date
03/07/2015

Recruitment status
No longer recruiting

Registration date
13/07/2015

Overall study status
Completed

Last Edited
18/08/2023

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Tendinopathy is a medical term used to describe painful conditions occurring to and around tendons due to overuse. It can result in pain, disability, depression and anxiety. The rotator cuff tendons (group of tendons in the shoulder) are commonly affected, particularly in people over the age of 50. Despite mixed and limited evidence, several non-surgical treatment approaches have been used to treat the condition, including non-steroidal anti-inflammatory drugs, eccentric strengthening exercises, corticosteroid injections, extracorporeal shock wave therapy and platelet rich plasma (PRP) injections. PRP injections are an emerging therapeutic approach that have been used in a variety of clinical areas, including dermatology, plastic surgery, sport medicine, dentistry and orthopedic surgery. Platelets are cells that contain over 300 bioactive proteins and growth factors that control cell growth and differentiation, synthesis of connective tissue, and revascularization (restoring of a blood supply to an area of the body where the circulation has been blocked). In tissues that are aging and do not repair or regenerate well, growth factors may also help to improve healing. PRP injections have been used as a treatment for tendinopathy and have been shown to relieve pain and disability. A recent systematic review of tendinopathy (i.e. a review of all the literature published in the area) found that pain was significantly reduced up to 1-year following PRP injections. However, the quality of the methods used has varied across the studies, with several limitations commonly observed such as lack of a control group, or small number of participants. Research has started to examine the effect of PRP injections for treating rotator cuff tendinopathy. Of these studies, findings and methodological quality have also varied, making it difficult to decide if PRP injections work well as a treatment or not. Prior to conducting a full scale randomized controlled trial to clarify the effectiveness of this treatment for rotator cuff tendinopathy, it is important that pilot studies to be run to provide background information to help overcome limitations of previous studies. The aim of this study was provide this information to assist in the planning of these large-scale studies.

Who can participate?
Patients aged between 35-60 diagnosed with rotator cuff tendinopathy for at least 3 months and not responding to treatment.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 are assigned to the PRP group. Those in group 2 are assigned to the control group. All participants have a clinical and ultrasound assessment of the rotator cuff by one of the two physician investigators to correlate ultrasound findings to those demonstrated on MRI. Participants in group 1 are then given 4 ml of platelets to the damaged area of the tendon under ultrasound guidance. Participants in group 2 are injected in the same manner with 4ml of saline. Following the injection, all patients do a 3-month standardized, home-based daily exercise program under the supervision of a physical therapist. All participants are then clinically re-evaluated at 3, and 6 months after the injection.

What are the possible benefits and risks of participating?
Potential benefits include improved signs and symptoms of the tendinopathy (i.e. reduced pain and disability). Potential risks include side-effects of the injection such as infection or increased pain.

Where is the study run from?
Glen Sather Sport Medicine Clinic (GSSMC) in Edmonton, Alberta, Canada

When is the study starting and how long is it expected to run for?
July 2011 to July 2014

Who is funding the study?
Workers' Compensation Board of Alberta (Canada)

Who is the main contact?
Dr Douglas P. Gross
dgross@ualberta.ca

Contact information

Type(s)
Scientific

Contact name
Dr Douglas Gross

Contact details
2-50 Corbett Hall
University of Alberta
Edmonton
Canada
T6G 2G4
7804922690
dgross@ualberta.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A pilot study evaluating the effectiveness of platelet-rich plasma therapy for treating degenerative tendinopathies

Study objectives
This pilot project aimed to provide background information to assist in planning large-scale studies aimed at determining the effectiveness of platelet-rich plasma (PRP) injection on clinical and functional outcomes. We hypothesized that evaluating a single intratendinous, ultrasound-guided platelet rich plasma (PRP) injection into the degenerate rotator cuff would decrease pain, increase function and alter MRI-detected signs of tendinopathy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The University of Alberta Health Research Ethics Board, 27/04/2011, ref: Pro00019481

Study design
Single-centre interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

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

Interventions
Patients enrolled in the trial were randomly assigned to either a PRP or placebo control group by pulling group assignment out of a box without replacement. At the time of enrolment, all

participants had a repeat clinical and ultrasound assessment of the rotator cuff by one of the two physician investigators to correlate ultrasound findings to those demonstrated on MRI. Using the Harvest™ system (Plymouth, Massachusetts) for generating PRP, 4 ml of platelets were fenestrated to the degenerative area of the tendon under ultrasound guidance for each patient in the study group. Patients in the placebo group were injected in the same manner with 4ml of saline. Following the injection, all patients undertook a 3-month standardized, home-based daily exercise program under the supervision of a physical therapist. Patients were clinically re-evaluated at 3, and 6 months post-injection.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome measure
Since PRP treatment aims to facilitate tendon healing, reduce pain and increase functional ability, we measured self-report pain intensity and disability using self-report outcome measures as described below, as well as objective clinical evaluations that included assessment of the pre- and post-injection MRI findings. Musculoskeletal radiologists evaluated the MRI results qualitatively and quantitatively where possible using size of the tear in millimeters. MRI was conducted before the injection then repeated 6 months following the study PRP injection. Post-injection findings were compared to pre-injection findings by the assessing radiologist.
1. Three 10-point VAS measures were used in all patients to measure pain intensity, ability to do daily activities, and physical activity/exercise. These were anchored at 0 with ‘no pain’ and 10 ‘worst imaginable’. These scales were completed before injection and at each follow-up. The minimum clinically important difference for the 10-point VAS was considered to be 1.5/10.
2. We also measured disability and health-related quality of life using the Disabilities of the Arm Shoulder and Hand (DASH) and Western Ontario Rotator Cuff (WORC) Index questionnaires. These were completed before injection and at each follow-up assessment. The DASH questionnaire is a commonly used, self-report, region-specific outcome instrument developed as a measure of self-rated upper-extremity disability and symptoms. The DASH consists mainly of a 30-item disability/symptom scale, scored from 0 to 100. The Western Ontario Rotator Cuff (WORC) Index questionnaire is a self-report questionnaire consisting of 21 items representing 5 domains to assess disease-specific quality-of-life. There are 6 questions in the physical symptoms domain, 4 in the sports and recreation domain, 4 in the work domain, 4 in the lifestyle domain, and 3 in the emotions domain. All DASH and WORC scores were converted into a standardized score out of 100. Lower DASH scores indicate less disability while higher WORC scores indicate higher life quality. The minimum clinically important difference for the DASH and WORC were considered to be 15/100.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/07/2011

Completion date

31/12/2015

Eligibility

Key inclusion criteria
Patients with rotator cuff tendinopathy treated at the Glen Sather Sport Medicine Clinic (GSSMC) in Alberta, Canada, between July 2011 and July 2014 were assessed for eligibility. Inclusion criteria were:
1. Patients between 35 and 60 years of age
2. Minimum of 3-month history of non-traumatic shoulder pain that was unresponsive to previous conservative treatment (including analgesia, subacromial steroid injection and physical therapy)
3. Tendinosis/tendinopathy or partial thickness tears in the supraspinatus and/or infraspinatous tendons confirmed using Magnetic Resonance Imaging (MRI). All participants had MRI of the affected shoulder prior to referral for consideration of enrolment in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
35 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
We aimed for 50 but successfully enrolled 9.

Key exclusion criteria
Patients were excluded if they had:
1. A history of rotator cuff repair
2. Traumatic injury to the shoulder inducing pathology
3. MRI findings showing full thickness rotator cuff tear
4. Previous PRP treatment for the rotator cuff
5. Shoulder pain due to a work-related injury/complaint
6. Diabetes

Date of first enrolment
01/07/2011

Date of final enrolment
31/07/2014

Locations

Countries of recruitment
Canada

Study participating centre
Glen Sather Sports Medicine Clinic
University of Alberta
Level 2, Kaye Edmonton Clinic
11400 University Avenue
Edmonton
Canada
T6G 1Z1

Sponsor information

Organisation
University of Alberta Rehabilitation Research Centre

Sponsor details
8205 114 St
3-62 Corbett Hall
Edmonton
Canada
T6G 2G4
780-492-2690
rrc@ualberta.ca

Sponsor type
Research organisation

Website
http://rehabilitation.ualberta.ca/research/institutes-and-centres/rehabilitation-research-centre

ROR
https://ror.org/0160cpw27

Funder(s)

Funder type
Industry

Funder Name
Workers' Compensation Board of Alberta

Results and Publications

Publication and dissemination plan
Findings will be published in a peer-reviewed journal in 2015 or 2016.

Intention to publish date
01/10/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/02/2016		Yes	No
Protocol (other)	Full Study Protocol for Observational Cohort Study (Study 2)	05/02/2016	18/08/2023	No	No
Protocol (other)	Full Study Protocol for Randomized Control Trial (Study 1)	05/02/2016	18/08/2023	No	No