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The effect of platelet-rich-plasma (PRP) injection on recovery from grade-2 hamstring tear

Submission date
22/05/2019

Recruitment status
Suspended

Registration date
28/05/2019

Overall study status
Completed

Last Edited
24/08/2020

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Muscle strains are one of the commonest injuries affecting athletes. It accounts for up to 30% of the injuries sustained in sports events. The majority of muscle injuries are caused by contusion or excessive strain of the muscle especially in sports that require sprinting or jumping activities. Despite its frequent occurrence, the best treatment for muscle strains is still not clearly defined. Various interventions have been suggested but only few are supported by evidence from well-designed studies. In the acute phase following muscle injuries the treatment objectives include to limit extent of injuries, minimise swelling and control pain. Despite various approached used, duration to return to play (DRP) ranges from 6 weeks to never, with large variability based on severity of the strains. More recently researchers are exploring in using biologicals products in an attempt to accelerate muscle healing. Biologicals products such as autologous blood injection, platelet-rich plasma, and preparation rich in growth factors had demonstrated promising results for muscle injuries in animal trials. Evidence to suggests similar effects in human is limited and showing inconsistencies results.
The main objective of this study is to compare the effect of a single injection of platelet-rich plasma (PRP) with Normal saline (Control). The study will be conducted at the National Sports Institute (NSI) of Malaysia Sports Medicine Clinic.

Who can participate?
Athletes who are 18 years and above who have sustained a grade-2 hamstring muscle tear are eligible to participate in this study.

What does the study involve?
Selected patients will be divided random into PRP and Control groups. Patient in the PRP group will receive a single injection of PRP into the injured area under ultrasound guidance. Whereas, patient in the Control group will receive normal saline injection using the same technique. Patients from both groups are require attending their daily rehabilitation session (5 days /week) at the Physiotherapy Unit, NSI of Malaysia.
Patients progress will be monitored on a weekly basis until full recovery achieved upon which patients are allowed to return to their pre-injury training activities. All patients will be follow-up

until they have fully recovered. Patients will be contacted once a month for the next 6 months following recovery for injury recurrence.

What are the possible benefits and risks of participating?
By participating in this study, patients might recover from the injury in a shorter time. Such information could be use as a guide for the treatment of muscle injury.
Since the PRP produced in this study are extracted from patients own blood, we do not anticipate any significant drawbacks on any of the participants except for some pain during blood withdrawal.

Where is the study run from?
National Sports Institute of Malaysia Sports Medicine Clinic, Kuala Lumpur, Malaysia.

When is the study starting and how long is it expected to run for?
We plan to start the study in September 2019 and hope to complete the data collection in December 2021.

Who is funding the study?
The study is funded by the NSI Research Grant (ISNRG 002/2017) and researchers will cover any expenses.

Who is the main contact?
Assoc. Prof. Dr. Mohamad Shariff Bin A Hamid,
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effects of platelet-rich-plasma (PRP) vs. saline Injections on the duration of return-to-play after grade-2 hamstring tear: A randomised control trial

Study objectives
1. There is a significant difference in the recovery time following acute muscle injury in athletes receiving platelet-rich plasma (PRP) injection therapy combined with standard rehabilitation program compared with athlete receiving a normal saline injection with a standard rehabilitation program.
2. The PRP intervention group will demonstrate a faster recovery time than the placebo control group
3. The PRP intervention group will demonstrate lesser recurrence of muscle injury at six months' follow-up period than the placebo control group

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/07/2016, University of Malaya Medical Research Ethics Committee (Pusat Perkhidmatan Penyelidikan [PPP], Tingkat 2, Institut Pengurusan & Perkhidmatan Penyelidikan [IPPP], University of Malaya, 50603, Kuala Lumpur, Malaysia; 03-79677022 (ext : 2369); umrec@um.edu.my), ref: 20166-2533.

Study design
SIngle centre double-blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Grade-2 hamstring tear

Interventions
Treatment
1. SIngle 3ml injection of platelet-rich-plasma (PRP) into the injured area under ultrasound guided injection
2. Single 3ml injection of normal saline (Control) into the injured area under ultrasound guided injection.

Randomisation process
A computer-generated block randomization of eight was used to create a randomization schedule (www.randomization.com). Subjects were randomised into either PRP injection with standard rehabilitation program (PRP group) or normal saline (NS) injection combined with rehabilitation program (Control group)

1. Eligible patients (following the screening process) for inclusion in the study are required to:
1.1 Complete a clinical research form which collects athletes sociodemographic, sporting history, and information about the current injury (mechanisms of injury, where and when the injury occurs, etc)
1.2 Brief Pain Inventory Questionnaire – Short Form (BPI-SF)
1.3 Undergo clinical assessments by a physiotherapist who is blinded of the participants' treatment group
1.3.1 Hamstring palpation – the area of tenderness/pain will be measured from the ischial tuberosity
1.3.2 Active knee extension test – to assess hamstring flexibility (compare with the uninjured side)
1.3.3 Resisted knee flexion at 15 degrees (in prone position)
1.4 Participants are then randomly divided into PRP or Saline (Control group)

2. In the PRP group:
2.1 Following randomisation, a 56 ml of blood will be extracted from athletes' antecubital vein. Fifty-four ml of the blood will be transferred into a 60 ml syringe primed with ACD-A. The blood collected for PRP will be prepared using a commercial PRP kit according to the manufacturer guide. The PRP kit could produce approximately 6 ml of PRP.
2.2 In this study, 3 ml of extracted PRP will be injected into the injured area under ultrasound guidance with syringe covered to ensure participants remain blinded to the intervention. One ml will be sent to the hospital laboratory for platelets, red blood cell and leucocyte count, while the remaining 2 ml were stored in -20° Celsius for analysis of growth factors (basic fibroblast growth factor [bFGF]; insulin-like growth factor-1 [IGF-1]; transforming growth factor-β1 [TGF-β1]), which will be performed in a private laboratory later.

3. In the Control group:
3.1 Following randomisation, a 56 ml of blood will be extracted from athletes' antecubital vein. Two milliliters of the blood collected from participants randomized to NS group will be sent to the laboratory for full count analysis including red blood cell (RBC), platelet and white blood cells (WBC) quantifications. The remaining 54 ml will be used to evaluate a cost-effective technique of PRP preparation (without commercial kit) using consumables readily available in a typical clinical setting. The PRP prepared using this method will also be sent to the laboratory for analysis of cellular and growth factors components.
3.2 Participants in the control group will receive a single three ml injection of normal saline with syringe covered to ensure participants remain blinded to the intervention. All injections will be administered under ultrasound guidance using aseptic technique.

4. Additionally, participants in both PRP and Control groups will be required to attend a standardised hamstring rehabilitation program (progressive agility and trunk stabilization PATS) attended by a trained sports physiotherapist. The physiotherapy session will commence at Day 3 following injection.

5. Participants in both groups are required to attend to a once a week follow-up assessment until fully recovered, at each follow-up participants are required to complete:
5.1 BPI-SF questionnaire
5.2 Clinical assessment as mentioned in 1.3

6. Once fully recovered (meeting set of clinical as well as objective assessment (isokinetic testing) participants are allowed to resume full activities as they were before the injury.

7. Participants will be contacted via telephone at 6 months after recovery to explore recurrence of a hamstring injury.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Primary outcome(s)
Duration of return-to-play (DRP). DRP is defined as the duration (in days) from the date of injury onset until the participants fulfilled the return-to-play (RTP) criteria.

Key secondary outcome(s))
1. Pain measured using the Brief Pain Inventory–Short form (BPI-SF) at baseline and then once a week (at follow-up assessment) until participants have fully recovered.
2. Recurrence of injury within the next 6 months following recovery. Participants will be monitored via telephone on a monthly basis for 6 months following RTP, in the event of suspicion of re-injury, participants were advised to consult the clinic and the study coordinator as soon as possible. Acute hamstring injury over the same site occurring within the first 6 months following RTP was classified as re-injuries.

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Grade-2 hamstring injury diagnosed on clinical assessment and confirmed on ultrasonography
2. Aged ≥ 18 years
3. Acute hamstring muscle injury (≤ seven days)
4. Able to understand and follow the study protocol and had completed the written informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Previously received any form of injection therapy for the current injury
2. Using anti-inflammatory drugs (NSAIDs) within one week before randomization
3. Unable to fulfill weekly follow-up appointments and comply rehabilitation program
4. Significant cardiovascular, renal, hepatic disease, malignancy, history of anemia, and previous muscle surgery

Date of first enrolment
03/09/2019

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Malaysia

Study participating centre
National Sports Institute of Malaysia Sports Medicine Clinic
Bukit Jalil
Kuala Lumpur
Malaysia
57000

Sponsor information

Organisation
National Sports Institute of Malaysia

Funder(s)

Funder type
Government

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Mohamad Shariff A Hamid (ayip@um.edu.my): the primary outcome (duration of return to play), the secondary (Brief Pain Inventory scores, injury recurrence) and other outcomes (PRP characteristics, adverse events). Data will become available after findings have been published and kept for 7 years after study completion. Data will be shared through email for meta-analyses upon consent from the National Sports Institute of Malaysia, data anonymisation must be ensured.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/08/2020	24/08/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes