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Enhancing muscle healing using platelet-rich plasma (PRP) injection

Submission date
16/08/2011

Recruitment status
No longer recruiting

Registration date
25/08/2011

Overall study status
Completed

Last Edited
15/08/2014

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 most common injuries affecting athletes. Most muscle injuries are caused by contusion (bruising) or excessive strain of the muscle, especially in sports that require sprinting or jumping activities. The best treatment for muscle strains is still not known. Various treatments are being used with limited evidence. Current approaches include rest, ice, compression and elevation (RICE) together with a short period of immobilization during the early stage after injury. Despite these, the time to full recovery is still lengthy (between 6 weeks to never). The median time to full return to play in Malaysian athletes was 45 days. Within the last 5 years, there has been a growing interest in the use of platelet-rich plasma (PRP) for muscle injuries. Several reports have suggested that PRP may accelerate muscle healing and allow earlier return to play. The main aim of this study is to determine the effectiveness of a single injection of platelet-rich plasma (PRP) for the treatment of muscle injury.

Who can participate?
Patients aged 18 and over who have been diagnosed with a muscle injury within the last 5 days

What does the study involve?
After giving your written consent to participate in the study you will be asked to fill in a set of questionnaires about yourself and your injury. An ultrasound examination will be conducted to confirm your injury. Participants diagnosed with grade 2 muscle injury will be randomly divided into two groups. Participants in both groups will need to follow a standard muscle injury rehabilitation program under the supervision of a sports physiotherapist at the Sports Clinic, University Malaya Medical Centre. In addition, 50 ml of blood will be withdrawn from patients in Group 2. The blood will be processed to obtain platelet-rich plasma (PRP). The PRP obtained will be injected under ultrasound guidance into the injured muscle. A small amount of local anaesthetic will be given prior to PRP injection. Participants are allowed to take paracetamol when necessary. Participants from both groups will be monitored on a weekly basis until full recovery or the end of week 16.

What are the possible benefits and risk of participating?
You may recover from the injury faster, and since the PRP is extracted from your own blood and the injection is done using a clean technique we do not anticipate any major risk for any of the

participants in this study. Participants may experience some pain during PRP injection or during the blood taking process.

Where is the study run from?
The Sports Medicine Clinic, University Malaya Medical Centre, organizes the study.
Two outpatient clinics are involved: the Sport Medicine Clinic at the University Malaya Medical Centre, and the Sports Clinic at the National Institute of Sports of Malaysia.

When is the study starting and how long is it expected to run for?
The study will be open to participants from November 2011 until January 2013.

Who is funding the study?
University of Malaya (Malaysia).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
835.11

Study information

Scientific Title
Platelet-rich plasma (PRP) injection for the treatment of grade 2 muscle injury: a randomised single-blinded clinical trial

Acronym
PRP- RTP

Study objectives
1. There is a significant difference in the recovery time following acute muscle injury in patients receiving platelet-rich plasma (PRP) injection therapy compared with patient receiving rehabilitation therapy only.
2. The PRP intervention group will demonstrate a faster duration to return-to-play (RTP) than the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee, University Malaya Medical Centre, 25/02/2011, MEC Ref. No: 835.11

Study design
Randomised single-blinded trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Muscle injury

Interventions
Eligible injured athletes were randomised using computer block randomisation software into two groups:
1. Control group (C)
2. PRP group (PRP)

Control group
Participants in the control group will receive a standard physiotherapy treatment (attended by a trained sports physiotherapist). This consists of the use of cryotherapy, range of motion (ROM) and muscle strengthening exercises. In addition the use of non-steroidal anti-inflammatory drugs (NSAIDs) will not be allowed throughout the study. The use of oral paracetamol however is allowed.

PRP group
In addition to the standard physiotherapy treatment participants in this group will receive a single PRP (3 mls) injection into the site of injury. The PRP will be extracted from participants own blood. The use of non-steroidal anti-inflammatory (NSAIDs) will not be allowed throughout the study. The use of oral paracetamol however is allowed.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

1. Duration to full recovery (return-to-play)
Criteria for RTP:
1.1. Muscle strength: at or near pre-injury levels or symmetrical with unaffected site
1.2. Range of motion: at or near pre-injury levels or symmetrical with unaffected site
1.3. Tenderness: injury site should be non-tender
1.4. Inflammation or swelling: no swelling or inflammation

Outcomes are measured on a weekly basis until full recovery of the end of week 16

Key secondary outcome(s))
1. Level of platelets - blood and PRP
2. Level of growth factors in PRP
2.1. Insulin-like growth factor (IGF-1)
2.2. Transforming growth factor (TGF)-beta
2.3. Basic fibroblast growth factor (FGF)
2.4. Platelet-derived growth factor (PDGF)
3. Isokinetic muscle strength
4. Brief pain inventory - Short form (BPI-SF)

Outcomes are measured on a weekly basis until full recovery of the end of week 16

Completion date
01/01/2013

Eligibility

Key inclusion criteria
1. 18 years old and above
2. Acute muscle injury (less than 1 week)
3. Able to understand study protocol and informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Received any form of injection therapy
2. Using non-steroidal anti-inflammatory drugs (NSAIDs) within 1 week prior to randomisation
3. Unable to fulfill follow-up schedule

4. Significant cardiovascular, renal, hepatic disease, malignancy, history of anemia or previous muscle surgery

Date of first enrolment
01/11/2011

Date of final enrolment
01/01/2013

Locations

Countries of recruitment
Malaysia

Study participating centre
Unit of Sports Medicine
Kuala Lumpur
Malaysia
50603

Sponsor information

Organisation
University Malaya Medical Centre (Malaysia)

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
University/education

Funder Name
University of Malaya (Malaysia)

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/08/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes