

Clinical outcomes of platelet-rich plasma and bone marrow aspirate concentrate on repair of rotator cuff tears

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Registration date 27/08/2024	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/07/2024	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Interest in orthobiologics (injectable therapies developed from natural substances) for musculoskeletal disorders, particularly blood-derived products from the same individual (autologous), such as platelet-rich plasma (PRP) and bone marrow aspirate concentrate (BMAC), has surged in recent years. Despite promising results, standardized protocols and robust evidence remain elusive. While the effects of PRP on cartilage, bone, and muscle have been established, its role in rotator cuff tear treatment remains unclear. BMAC, while demonstrating promising regenerative potential, has less clinical trial data than PRP. Both therapies offer distinct repair mechanisms. This study aimed to evaluate the impact of BMAC+PRP on the recovery process following arthroscopic surgery for large rotator cuff tears.

Who can participate?

Patients aged 18 years old and over diagnosed with a massive tear (2-5 cm) of the chronic rotator cuff tendon

What does the study involve?

Participants will be randomly allocated to one of three groups. Those in group 1 are administered PRP injections. Those in group 2 are administered a BMAC+PRP injection. Those in group 3 are the control group. Assessments of clinical outcomes will be carried out at 3 and 6 months.

What are the possible benefits and risks of participating?

Patients may experience improvement or no improvement in symptoms.

Where is the study run from?

Department of Department of Orthopedic Surgery, Hallym University Kangnam Sacred Heart Hospital, School of Medicine Hallym University, Republic of Korea

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

March 2019 to September 2023

Who is funding the study?
Hallym University Medical Center (South Korea)

Who is the main contact?
Prof Kyu-Cheol Noh, happyshoulder@hallym.or.kr

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Protocol serial number

Mighty HAllym 4.0 (MH 4.0)

Study information

Scientific Title

Clinical outcomes of the Synergistic Potential of PRP and BMAC on repair of large-sized tear

Study objectives

Chronic rotator cuff tears are a widespread musculoskeletal disorder that affects approximately 21% of the population, causing significant pain, functional limitations, and muscular weakness in the shoulder joint. Surgical repair is often used for larger or symptomatic tears but has limitations. Despite advancements in surgical techniques, factors such as poor tendon vascularization, compromised tendon quality, and individual patient characteristics can hinder healing, leading to significant retear rates after repair. The retear rates reported in the literature vary widely in previous reports. Moreover, the success rate of rotator cuff repair after surgery can be as low as 0% and as high as 78%, with decreasing success rates as tear size increases.

It is hypothesized that both platelet-rich plasma (PRP) and bone marrow aspirate concentrate (BMAC) have individual orthobiologic potential and an enhanced synergistic effect on rotator cuff tear healing.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 01/05/2023, Ethics committee name of Hallym University Medical Center (Hallym University, Chuncheon, 24254, Korea, South; +82-31-380-1975; ds1024@hallym.or.kr), ref: 138-82-02667

Study design

Prospective randomized comparative study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Large (2-5 cm in width) chronic rotator cuff tear

Interventions

Patients will be randomly allocated to a control group, a bone marrow aspirate concentrate (BMAC)+platelet-rich plasma (PRP) group and a PRP-only group. Randomization will be performed using a predetermined block size to ensure balance between the groups. All surgical procedures will be performed under general anesthesia by a senior surgeon in the lateral decubitus position.

BMACs and PRP will be extracted from patients in the BMAC+PRP group, while the PRP group will only have PRP extracted. Bone marrow aspirates are obtained (48 ml + 6 ml ACD-A anticoagulant) and centrifuged using a BIOMET MarrowStim™ Mini kit (Biomet Biologics, Inc., Warsaw, IN, USA) to isolate concentrated BMACs. Peripheral blood (54 ml + 6 ml ACD-A anticoagulant) was collected from the left antecubital vein and centrifuged using a BIOMET GPS™ III kit (Biomet Biologics, Inc.) to extract PRP.

After obtaining BMACs and PRP, 2 ml of BMACs are mixed with 2 ml of PRP in a 10-ml syringe. The BMAC+PRP injection was then administered to the patients at the tear site under ultrasound guidance by an experienced physiatrist. No physical therapy was provided to confirm the therapeutic effects of BMAC+PRP. Whereas, the patients in the PRP group will be injected with 2 ml of PRP.

Clinical examinations will be performed preoperatively and at three and six months postoperatively.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Pain will be measured using the VAS at baseline (pre-surgery), 3 months and 6 months post-surgery .
2. Shoulder function will be measured using the ASES Shoulder Score at baseline (pre-surgery), 3 months and 6 months post-surgery.

3. Pain and ability to carry out normal daily activities will be measured using the constant score at baseline (pre-surgery), 3 months and 6 months post-surgery

Key secondary outcome(s)

1. MRI assessment of the supraspinatus, infraspinatus evaluates Muscle volume, Goutallier score of muscle atrophy and fatty infiltration at baseline (pre-surgery) and 6 months post-surgery.
2. Shoulder ultrasound examination evaluates rotator cuff tear size and lesion in millimeters at baseline (pre-surgery) and 3 weeks 3 months post-surgery

Completion date

01/09/2023

Eligibility

Key inclusion criteria

1. Patients aged at least 18 years
2. A large (2-5 cm in width) chronic rotator cuff tear confirmed by preoperative magnetic resonance imaging (MRI)
3. No history of shoulder surgery within the past 3 months
4. No abnormal findings on simple radiography, repair via arthroscopy
5. No abnormalities in blood coagulation or routine laboratory examination
6. No history of steroid injection within the past 3 months
7. No history of malignancy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

72 years

Sex

All

Total final enrolment

93

Key exclusion criteria

1. Subscapularis tendon disruptions (> 1/2 width)
2. Revision surgery
3. Inflammatory or autoimmune diseases

4. Reoperation due to re-tear
5. Other body parts operated within 6 months before and after rotator cuff repair
6. Any other associated shoulder lesion
7. Other severe medical problems, such as malignancy, respiratory disease, and preexisting coagulopathy
8. Positive urine pregnancy test in fertile women
9. Recent steroid injection within the past 3 months
10. Patients who refused to provide consent
11. Those who had difficulty partaking in clinical trials by the responsible investigator
12. Patients with cuff retraction or atrophy

Date of first enrolment

01/06/2019

Date of final enrolment

01/05/2023

Locations

Countries of recruitment

Korea, South

Study participating centre**Department of Department of Orthopedic surgery**

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Sponsor information

Organisation

Hallym University

ROR

<https://ror.org/03sbhge02>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hallym University Medical Center

Alternative Name(s)

HUMC

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Korea, South

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analyzed during this study will be included in the subsequent results publication

IPD sharing plan summary

Published as a supplement to the results publication