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

Submission date
17/05/2024

Recruitment status
No longer recruiting

Registration date
27/08/2024

Overall study status
Completed

Last Edited
16/07/2024

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
Prof Kyu-Cheol Noh

ORCID ID
https://orcid.org/0000-0001-8738-2977

Contact details
Director, HAllym University Dongtan Sacred Heart Hospital
7, Keunjaebong-gil
Hwaseong-si
Korea, South
18450
+82-31-8086-2010
happyshoulder@hallym.or.kr

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Medical and other records

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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 measure
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

Secondary outcome measures
1. MRI assessment of the supraspinatus, infraspinatous 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

Overall study start date
01/03/2019

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

Age group
Mixed

Lower age limit
18 Years

Upper age limit
72 Years

Sex
Both

Target number of participants
100

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
Hallym University Kangnam Sacred Heart Hospital, School of Medicine Hallym University
1, Singil-ro, Yeongdeungpo-gu
Seoul
Korea, South
07441

Sponsor information

Organisation
Hallym University

Sponsor details
1 Hallymdaehak-gil, Chuncheon-si, Gangwon-do
Chuncheon
Korea, South
24252
+82-33-248-1000
ghkim@hallym.ac.kr

Sponsor type
University/education

Website
https://www.hallym.ac.kr/

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

Publication and dissemination plan
1. Study protocol
2. Trial findings
Planned publication in a high-impact, peer-reviewed journal.

Intention to publish date
01/05/2025

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