Research Protocol

2020-03-01

1. Research Title

Atelocollagen & Hyaluronic acid correlation with enhancement of rotator cuff healing: Synergistic effect? 2-Year Results of a Randomized Controlled Trial

2. Principal Investigator

Hallym university dongtan Sacred Heart Hospital
Associate Professor of Orthopaedics
JEUNGYEOL JEONG

3. Background and Purpose of the research

The purpose of this study is to analyze the correlation by comparing the clinical outcomes of using atelocollagen and hyaluronic acid (HA) alone versus in combination for promoting rotator cuff healing after rotator cuff repair surgery in patients.

4. Research Contents

Comparative analysis of the clinical outcomes and MRI results of using atelocollagen and hyaluronic acid (HA) alone versus in combination for promoting rotator cuff healing after rotator cuff repair surgery in patients.

Clinical outcomes were compared based on joint range of motion, VAS, and ASES scores. The degree of repair healing was assessed via MRI examination. All statistical comparisons were analyzed using one-way analysis of variance (ANOVA).

5. Eligibility Criteria

Inclusion Criteria:

- Age between 40 and 75 years
- Scheduled for arthroscopic surgery after an MRI confirmed a diagnosis of rotator cuff tear
- Willing to participate and provide informed consent

Exclusion Criteria:

- Previous surgery on the affected shoulder

- Severe glenohumeral arthritis (Hamada grade ≥ 3)
- Neurological disorder affecting shoulder function
- Massive rotator cuff tear (Tear size ≥ 5 cm)

6. Expected research period: 36 months

7. Research Methods

For patients diagnosed with a rotator cuff tear based on MRI results and scheduled for surgery, we explain this research upon admission the day before surgery. The research begins only for those who consent to participate. This study was conducted as a prospective randomized trial. Participants are divided into four groups, and the patient themselves cannot know which group they belong to. (Group A: Both Atelo Collagen + Hyaluronic Acid (HA) injection, Group B: HA alone injection, Group C: Atelo collagen alone injection, Group D: No injection). Atello collagen and hyaluronic acid injections are administered into the space between the bone and tendon after repair process is complete, concluding the procedure. This researh compares the clinical outcomes and MRI findings among these four groups. Follow-up results are compared by measuring joint range of motion, VAS score, and ASES score during outpatient follow-up visits at 3 months, 6 months, 1 year, and 2 years post-surgery. MRI examinations are performed and compared at 6 months and 2 years post-surgery.

A power analysis was performed with clinical outcomes of pain visual analog scale (PVAS) score, function visual analog score (FVAS), and American Shoulder and Elbow Surgeons (ASES) score. With these parameters, the study required 25 patients per group to achieve a power of 0.80 and a significance level of 5%. The expected dropout rate was 15% *(Correlation between American shoulder and elbow surgeons and single assessment numerical evaluation score after rotator cuff or SLAP repair. Arthroscopy 2015;31:1688-92.)*

8. Safety considerations for subjects (e.g., trial discontinuation, management of serious adverse events)

1) Pain and Heating sense may occur in the shoulder area after the injection.

2) Hypersensitivity reactions (allergic reactions; itching, redness, etc.) may occur due to the product.

Thorough preparation for the occurrence of these side effects. In the event of any accident or issue related to this research, this medical team shall assume responsibility. Should any adverse effects occur in connection with the examination, appropriate medical treatment shall be administered immediately.

9. Measures to Ensure Research Ethics (Compliance with the Declaration of Helsinki must be explicitly stated, and any additional requirements necessary to ensure the ethics of the research should be described)

Only patients who have signed the consent form will be included. Patient information security will be maintained with the utmost confidentiality, and all relevant laws and regulations (such as the Declaration of Helsinki) will be followed.

Hallym University Dongtan Sacred Heart Hospital

Patient Consent Form

1. I have received an explanation from the medical staff regarding the content of this research, and having understood its purpose, I have decided to participate in the research. I confirm that I may withdraw from this research at any time if I choose to do so, and that I will not suffer any disadvantage as a result. I declare that my decision to participate in this research is made of my own free will.

2. Furthermore, I hereby consent to the use of my examination results and other medical records for purely research purposes.

3. I understand that if I have any questions about the details of the clinical trial, I can ask the responsible person at any time and receive a sufficient answer.

4. I understand that I will receive a copy of this consent form.

Recipient's Name	Signature	Date (month/day/year)
Principal Investigator Name	Signature	Date (month/day/year)
Guardian or legal representative Name	Signature	Date (month/day/year)

5. Researcher Contact Information
   +82-031-8086-2410 Orthopedic Clinic (Associate Professor of Orthopedics, Jeungyeol Jeong)