

To Evaluate the Effectiveness of the Use of a Novel Crosslinking Hyaluronan Hydrogel on the Prevention of the Adhesion Occurrence After Anterior Talofibular Ligament Repair Surgery

NCT06826898

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| Status | RECRUITING |
| Phase | Not Applicable |
| Sponsor | Talent Cro Inc. |
| Enrollment | 50 participants |

Key Eligibility Criteria

Inclusion (1)

- Voluntarily participate and sign an informed consent form; 1.2 Age 18 to 60 years of male or female; 1.3 Patients experiencing lateral ankle pain discomfort, confirmed by MRI to have anterior talofibular ligament (ATFL) injury; 1.4 History of recurrent ankle inversion sprains three times or more, with no improvement after six months of conservative treatment, and scheduled for ATFL repair surgery; 1.5 Willing to comply with all follow-up requirements of the trial protocol.

Exclusion (1)

- Severe ankle osteoarthritis; 2.2 Patients with a history of ankle fracture or surgery; 2.3 Undergoing foot- or ankle-related treatments that may affect the trial results; 2.4 Presence of skin infection, skin defects, or need for skin grafting at the surgical site; 2.5 Uncontrolled chronic diseases, such as diabetes mellitus; 2.6 Presence of autoimmune diseases (such as Autoimmune Collagenopathy, rheumatoid arthritis), malignancies, coagulation disorders, heart diseases, psychiatric illnesses, or other conditions that may pose higher risks to patients in the trial; 2.7 Use of corticosteroids within the past 6 months, systemic corticosteroids within the past month, immunosuppressive drugs within the past 3 months, or daily use of non-steroidal anti-inflammatory drugs (NSAIDs) within the past week, or occasional use within 8 hours (patients using nasal/inhaled corticosteroids may be considered for inclusion) ; 2.8 Clinically significant coagulation abnormalities or undergoing anticoagulant therapy within 10 days before surgery or currently taking anticoagulant drugs; 2.9 Known allergy to sodium hyaluronate or any components of medical devices; allergy to Gram-positive bacterial protein or streptococcal protein or other severe allergic history deemed unsuitable for participation by the investigators; 2.10 Pregnant, lactating women, or women planning to become pregnant during the trial period; 2.11 Other conditions deemed unsuitable for participation by the investigators.

Locations (1 total)

Show Chwan Memorial Hospital, Changhua, Taiwan