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STUDY PROTOCOL

The Clinical Effect of Electroacupuncture Combined with Surround Needling in the Treatment of Acute Lateral Ankle Sprain Based on Musculoskeletal Ultrasound Imaging Technology: A Protocol for a Single-Centre, Randomized, Controlled Trial

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Objective: To verify the efficacy of electroacupuncture (EA) combined with surround needling on acute lateral ankle sprain (ALAS) based on musculoskeletal ultrasound (MSKUS) imaging technology.

Methods and Analysis: Sixty-six ALAS patients will be randomly divided into EA combined with surround needling group, sham EA group and ice combined with brake rest group in a 1:1:1 ratio by using a random number table. The Kofoed scores, MSKUS quantitative measurement and circumference of ankle joint will be compared to evaluate the differences in efficacy caused by the three treatment methods as stated. Data for the assessment will be collected at baseline, three-week treatment, and two-month follow-up in three groups of ALAS patients.

Trial Registration: ChiCTR-2300078874.

Keywords: acute lateral ankle sprain, electroacupuncture, musculoskeletal ultrasound imaging technology, protocol, randomized controlled trial, surround needling

Introduction

The ankle joint is composed of the articular surface of the tibia and fibula and the trochlea of talus, respectively. It is an important weight-bearing bone joint and most prone to injury.[1] With the improvement of living standards, outdoor activities are increasing, the incidence of AAS (acute ankle sprain) is increasing, it accounts for about 10%~15% of all sports injuries. Among them, lateral ligament injuries accounted for the vast majority, about 85%.[2,3]

Acute lateral ankle sprain (ALAS) represents a commonly sustained musculoskeletal injury, characterized by its high prevalence both within the general population and among individuals engaged in athletic activities.[4–6] Patients with ALAS frequently exhibit symptoms including erythema, edema, pain, and movement disorders localized around the ankle joint. These symptoms can progress to long-term chronic pain and dysfunction of ankle joint, significantly

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impairing the patients' daily activities and occupational performance.[7–11] Ankle sprains are typically categorized according to the extent of ligamentous injury. Grade I is mild ligament strain without visible rupture or joint instability. Grade II is a partial rupture of the ligament, often accompanied by moderate pain and swelling. There are functional limitations and varying degrees of ankle instability. The patient is unable to bear weight. Grade III refers to complete ligament rupture accompanied by obvious pain, swelling, hematoma, and pain. In grade III injuries, there are significant functional impairments and joint instability.[12,13] Depending on the severity of ankle damage, different levels of treatment (including surgery, immobilization, balance training, functional treatment with bandages, tape or different braces) will be selected.

Studies have shown that chronic pain in AAS patients is associated with an increased risk of anxiety, depression, and other adverse emotional states.[14] It mainly refers to the injury of lateral ligament of ankle, calcaneofibular ligament (CFL) and anterior talofibular ligament (ATFL), also known as ALAS.[12] Moreover, the clinical symptoms of ALAS greatly affect the quality of life of patients if the treatment is not timely or incorrect. It can lead to chronic ankle instability (CAI). The combination of treatment costs and sick leave contributes to a significant socioeconomic burden.[15–19] Consequently, addressing the pain management of patients with ALAS and improving their prognostic outcomes represents an urgent clinical challenge that requires immediate attention.

Currently, celecoxib capsules (Viatris Pharmaceuticals LLC, USA) are commonly used clinically to alleviate patients' pain, but prolonged use of this medication often results in diminished efficacy and may lead to severe adverse effects, such as gastric ulcer and liver damage. In the physical therapy methods commonly used by ALAS, the RICE principles are mainly followed and widely used in orthopedic clinical practice,[20,21] namely rest, ice, compression and elevation of the affected limb.[22] Despite this, the therapeutic effects are often transient, and some patients continue to experience persistent pain. With the continuous updating and application of clinical guidelines, this treatment plan is gradually no longer recommended.[23] Therefore, how to effectively relieve the persistent pain of ALAS patients is an urgent problem to be solved clinically.

In China, acupuncture has been developed as a therapeutic method for thousands of years. Recent clinical studies into the anti-inflammatory and analgesic properties of acupuncture have consistently demonstrated its efficacy in the treatment of musculoskeletal disorders. Multiple studies have shown that it has good therapeutic effects on inflammation, edema and pain. Ph.D. Zhang found that acupuncture reduces pain by desensitizing peripheral receptors and activating the opioid system.[24] Hahm's study on mice with ankle sprains showed that 2 hz electroacupuncture (EA) alleviated both pain and edema, while 100 hz only reduced pain. This highlighted acupuncture's effectiveness for ankle sprains and identified 2 hz as a more effective frequency. Hahm suggested that acupuncture's pain relief involves both opioid and non-opioid mechanisms.[25] Due to the immediate intervention effects of acupuncture treatment on ALAS, many emergency departments in countries with acupuncture techniques have adopted it as a therapeutic approach to mitigate redness, swelling, and pain, with promising efficacy outcomes.[26–28]

Musculoskeletal ultrasound (MSKUS) possesses distinct attributes such as dynamic, real-time, continuous visualization capabilities, quantitative and qualitative localization, ease of operation, and the absence of contraindications. Perone highlighted that MSKUS is popular among emergency department doctors for its versatility in examining joints, tissues, tendons, nerves, and fractures, offering immediate imaging and quick diagnosis.[29] Yuko Nakashima noted that advancements in MSKUS technology have enhanced clarity, allowing for radiation-free diagnosis of soft tissue issues. Compared to MRI, MSKUS is more time and cost-efficient, assesses muscle, tendon, and ligament damage, and provides insights into movement disorders by allowing patients to change positions.[30] Therefore, MSKUS plays a crucial role in evaluating musculoskeletal diseases.

At present, acupuncture is employed in the clinical treatment of ALAS in China; however, its use for ALAS on an international scale remains limited, despite recommendations from some experts. This limited adoption is primarily due to a lack of sufficient clinical trial evidence supporting the efficacy of acupuncture for ALAS.[31] Thus, we conduct this well-designed, single-centre, randomized controlled clinical trial to provide more robust guidance for the clinical application of acupuncture in the treatment of ALAS.

Materials and Methods

Study Design

The study is a single-centre, randomized controlled, outcome assessor-blinded clinical trial. It has received approval from the Ethics Committee of the Third Affiliated Hospital of Zhejiang Chinese Medical University. Sixty-six participants will be recruited in Zhejiang province, using a random number generator in Excel (version 2021, Microsoft, USA), with the groups randomly split (in a 1:1:1 ratio) into three (EA combined with surround needling group, sham EA group and ice combined with brake rest group). Patients in 3 groups will be treated for 3 weeks, followed up for 2 month. Data for the assessment will be collected at baseline, 3-week treatment, and 2-month follow-up in 3 groups of ALAS patients. This study protocol was developed according to the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) 2013, which is supplied in Supplementary Table 1. Chinese Trial Registry (ChiCTR) has registered this trial. The trial flow chart is summarized in Figure 1 and Table 1.

Study Methods

Participant Recruitment

Participants for this investigation will be enrolled from various regions within Zhejiang province. We will utilize WeChat and hospital notice boards as mediums for disseminating information about our research. The eligibility and clinical severity of ALAS patients will be evaluated by medical professionals who have undergone rigorous standardized training. Following the confirmation of eligibility, informed consent will be secured from patients who consent to engage in the study.

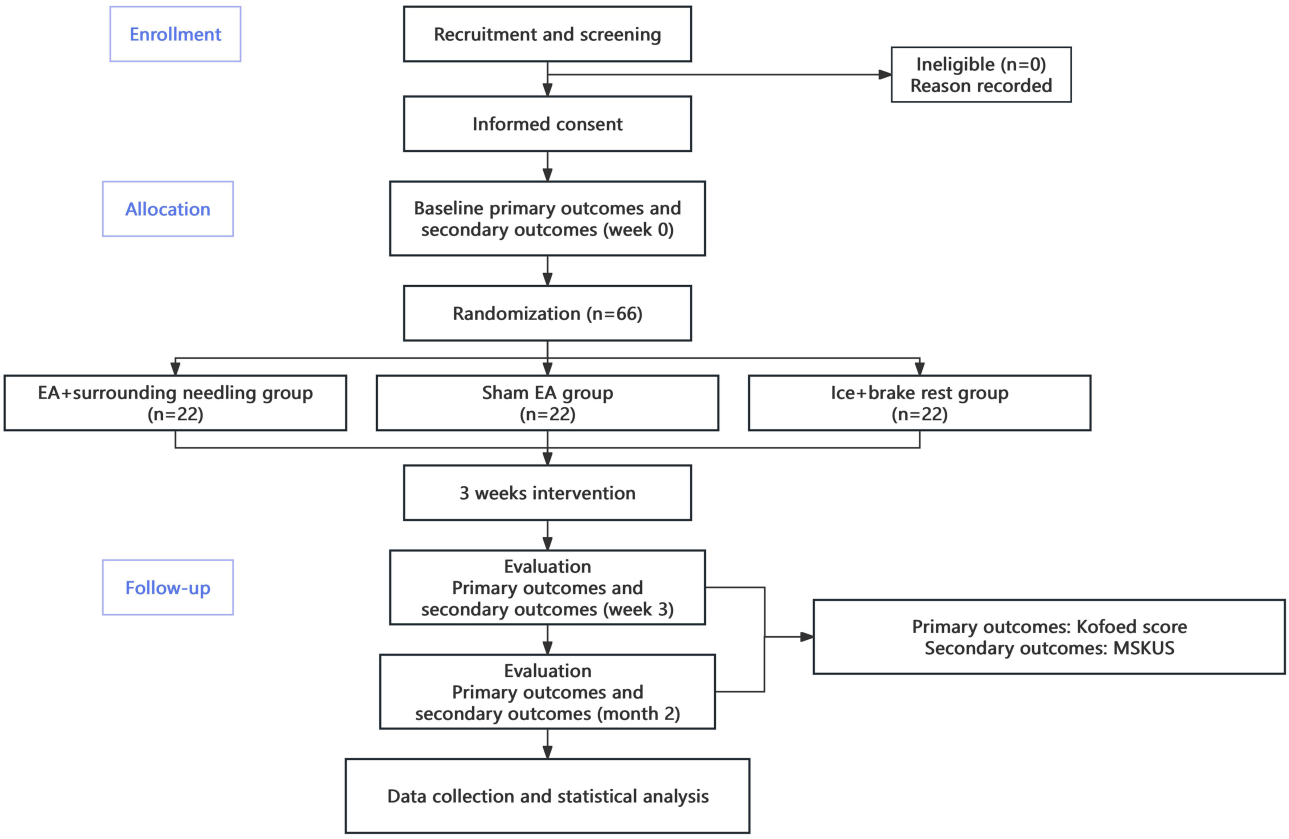

Figure 1 Route diagram of study design.
Abbreviations: ALAS, acute lateral ankle sprain; EA, electroacupuncture; MSKUS, musculoskeletal ultrasound.

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Table 1 Trial Schedule

Assessment	Screening	Baseline Week 0	Treatment Period Week 1	Treatment Period Week 2	Treatment Period Week 3	Follow-Up Week11
Informed consent	○					
Demographics	○					
Type of ALAS	○					
History of ALAS	○					
History of other diseases	○					
MSKUS assessment		○			○	○
Kofoed score		○	○	○	○	○
Adverse events					○	
Recurrence of ALAS						○

Note: ○, required.
Abbreviations: ALAS, acute lateral ankle sprain; EA, electroacupuncture; MSKUS, musculoskeletal ultrasound.

Ethical Considerations

Ethical approval from the review board will be secured before initiating this research. Participant privacy will be safeguarded, and all individuals will be enrolled in treatment and assessment protocols only after providing their informed consent.

Randomization and Blinding

Randomization for the study will be facilitated using Microsoft Excel 2021 software. The generated list of random numbers will be printed and subsequently divided into individual small segment. The randomizer will input the estimated sample size into the statistical software package, obtain the sequence number, create a random card, and seal it in an envelope. When subjects who meet the inclusion criteria enter the trial, the randomizer will open the envelopes in the order of their entry and follow the instructions on the randomization card to divide them into one group. Enabling the envelope is considered invalid and cannot be used again. When the case is not included, the envelope shall be kept by a dedicated person and cannot be opened in advance.

Due to the particularity of acupuncture operation, operators and patients will not be blinded. The efficacy evaluation will be conducted using a blind method, including MSKUS imaging, Kofoed score will be completed by inspectors who did not know the grouping information; The data summary stage will adopt blind statistical analysis, and the research results will be statistically analyzed by statisticians who are unaware of the grouping situation. Separate the research operator, efficacy evaluator, and outcome statistician.

Participants and Populations

Diagnostic Criteria for ALAS Patients

1) Have a history of ankle trauma.
2) Ankle pain, visible joint swelling and subcutaneous ecchymosis with limited joint movement.
3) Localized pressure pain is obvious, and the anterior and inferior ankle pain is aggravated when the foot is inverted.
4) X-ray film excludes ankle fracture and dislocation.

Inclusion Criteria

1) Meets the diagnostic criteria for a grade I or II injury.
2) Within 48 h of onset.
3) Age 18~60 years old, gender is not limited.

4) The skin of the affected ankle joint is intact, without breakage or ulceration.
5) Patients without serious cardiovascular system, respiratory system, immune system diseases, diabetes mellitus and mental diseases and other diseases.

Exclusion Criteria

1) Combined with ankle fracture.
2) Patients with grade III injuries or complete ligament ruptures.
3) Patients who cannot comply with the treatment program. Those with keloid, localized combined existence of other skin diseases, unsuitable for EA treatment operation.
4) Patients with serious combined cardiovascular, cerebrovascular, hepatic, renal, hematopoietic system diseases or systemic failure, patients with connective tissue disease, hemophilia, diabetes, malignant tumors, and patients with easy bleeding tendency.

Interventions and Comparison

The treatment period is 3 weeks, and the follow-up is 2 months. Patients need to receive treatment two or three times a week. The Kofoed score will be recorded after each treatment. MSKUS will be performed in 3 groups of ALAS patients before first treatment and after the 3-week treatment. The Kofoed score and MSKUS will be recorded after the follow-up period.

The Position and Function of Acupoints

In accordance with the 2006 People's Republic of China National Standard (GB/T 12346–2006) "Acupoints names and positioning", the locations and indications of acupuncture acupoints are detailed in Figure 2 and Table 2.

EA Combined with Surround Needling Group

For EA, stainless steel needles (size 0.25*40 mm, Huatuo brand, Suzhou Medical Appliance, China) will be inserted. Instruments of EA will be unified by Hans acupoint neural stimulator (HANS-200A, Nanjing Jisheng Medical Technology Co. Ltd, China). In accordance with *therapeutics of acupuncture and moxibustion*, the textbooks of TCM, patients belonging to the EA combined with surround needling group will undergo the insertion of authentic needles at precisely designated acupuncture points: BL60 (Kunlun), BL62 (Shenmai), KI6 (Zhaohai), ST41 (Jiexi), ST42 (Chongyang) and Ashi point, which need operators search for the acupoint based on the patient's the most painful location.

All treatments will be administered exclusively by acupuncturists who hold a master's degree and possess a minimum of five years of professional experience in acupuncture. Before the formal start of the trial, all acupuncturists will be trained in standardized operation to ensure that every acupoint have the sense of Deqi, BL60 and ST41 will be selected to receive EA. The EA parameters will be selected as 2/100Hz, and the treatment time will be 30 minutes. The acupuncture intensity will be tailored to each patient's tolerance and suitability. The intervention and its comparison will be conducted

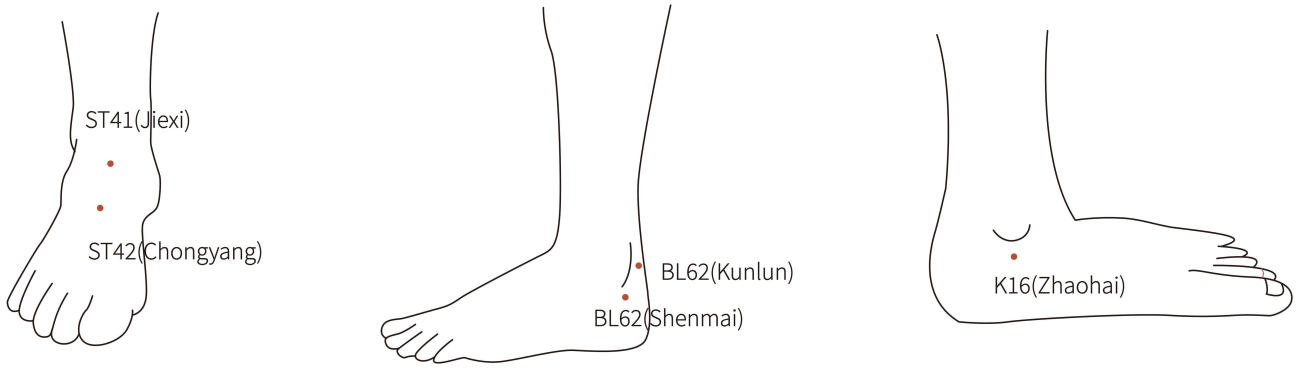

Figure 2 Location of acupoints.

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Table 2 Locations and Indications of Acupuncture Acupoints

Acupoint	Location	Major Indication and Function
BL60 (Kunlun)	In the depression between the tip of the external malleolus and tendo calcaneus.	1. Headache, neck stiffness, lumbosacral pain, swelling and pain of malleolus. 2. Epilepsy. 3. Difficult labor.
BL62 (Shenmai)	In the depression directly below the external malleolus.	1. Pain of the lumbar and leg. 2. Headache, dizziness. 3. Epilepsy, manic psychosis, insomnia.
KI6 (Zhaohai)	In the depression below the tip of the medial malleolus.	1. Insomnia, epilepsy. 2. Dryness and soreness of throat, redness, swelling and pain of the eye. 3. Irregular menstruation, leukorrhea, prolapse of uterus. 4. Retention of urine.
ST41 (Jiexi)	In the depression at the midpoint of the transverse crease of the ankle between the tendons of m. extensor hallucis longus and digitorum longus.	1. Paralysis or weakness of lower extremities, pain of ankle joint, foot drop. 2. Headache, dizziness. 3. Manic psychosis. 4. Abdominal distention, constipation.
ST42 (Chongyang)	At the highest point of the dorsum of foot, between tendons of m. extensor hallucis longus and digitorum longus, where the dorsal artery of the foot pulsates.	1. Atrophy and weakness of foot. 2. Gastric pain, abdominal distention. 3. Deviation of mouth and eye. 4. Manic psychosis.

in accordance with the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) 2010,[32] as detailed in Supplementary Table 2. During treatment, patients must wear relevant braces to maintain ankle joint immobilization.

Sham EA Group

Sham EA will be administered by blunt and retractable needles at acupoints as same as EA combined with surround needling group. After the acupuncturist inserts the needle into the tube, the needle will retract into the handle when the blunt tip touches the skin. There will be no getting Qi sensation. The manipulation techniques will be the same as in the EA combined with surround needling group with 30 min duration without needle penetration.

The acupoint selection of sham EA group will be the same as that of the EA combined with surround needling group. When inserting the needle, only the skin will be punctured, the needle will not enter the muscle layer and without Deqi. After inserting the needle, the EA device will not be turned on. The treatment time, frequency, and observation period will be the same as the EA combined with surround needling group. During treatment, the sham EA group will wear the same brace as the EA combined with surround needling group to maintain ankle joint immobilization.

Ice Combined with Brake Rest Group

Follow the RICE principle and apply ice within 48 hours of ALAS onset. Prepare ice packs and dry towels for the patient and instruct them to make them softer and easier to adhere to the skin. Seal and secure the towel to form an ice pack. Place the ice pack on the twisted area and apply it for no more than 20 minutes each time. At the same time, intermittently remove the ice pack from the twisted area to allow the skin to recover a little temperature, and then reapply. Advise the patient to apply ice packs three times a day.

After 48 hours, only use braces to maintain ankle joint immobilization without special treatment.

The treatment frequency and observation period will be the same as the above two groups.

Frequency, Duration, and Time

Treatment will be required three times a week, with an interval of 1 to 2 days between each session. Continuous treatment for 3 weeks, a total of 9 times. The baseline observation period will be 2 days, the treatment period will be 3 weeks, and the follow-up period will be 2 months. The total research period will be 11 weeks. The observation time points will be baseline before treatment, post-treatment, and 2 months after the end of treatment (follow-up).

Outcome Measures

Primary Outcome Measurement

The primary outcome is Kofoed score.[33]

Kofoed score is a scoring system used to assess ankle joint function, which mainly includes three parts: pain, function, and range of motion (ROM), each with specific scoring criteria. The part of pain has 50 points, and the score gradually decreases from 50 points (no pain) according to the different pain conditions of the patient's ankle joint. The part of function has 30 points, and the evaluation criteria include toe walking, heel walking, ability to climb stairs, etc. The score is evaluated based on whether these movements can be completed independently and the degree of assistance used. The part of ROM has 20 points, which evaluates the ROM of the ankle joint in extension, flexion, supination, and pronation, as well as the degree of eversion and inversion during weight-bearing. Different scores are given based on the size of the ROM. According to the Kofoed scoring criteria, the evaluation results of ankle joint function can be divided into four levels: excellent, good, moderate, and poor. Specifically, a score of 85–100 is excellent, 75–84 is good, 70–74 is moderate, and below 70 is poor. This scoring system is widely used in the assessment of ankle joint dysfunction, helping doctors and patients understand the functional status of the ankle joint and providing reference for treatment. The Kofoed score is widely used to assess the different degrees of ankle sprains in patients and their quality of life.[34–37]

Secondary Outcome Measurement

MSKUS is used as the examination method to mainly examine and compare the thickness of the lateral ankle ligament before and after treatment.[38] The HITACHI color Doppler ultrasound diagnostic instrument (ARIETTA60, HITACHI, JPN) will be used for high-frequency MSKUS examination of the ankle joint, with a linear array probe frequency of 7.5–5.0 MHz. If the patient's condition permits, the affected limb will be placed on the examination bed for multi section scanning of the lateral collateral ligament of the ankle joint. When scanning the anterior talofibular ligament, the patient will lie on their back with the foot flexed, and the probe will be placed at the back end on the outer ankle, with the front end inserted diagonally forward onto the talus. When scanning the calcaneal and fibular ligaments, the patient will lie on their side, with their foot dorsiflexion, and the probe will be placed between the lateral ankle and the calcaneus, at an angle of approximately 120° with the anterior talofibular ligament. When scanning the posterior talofibular ligament, the patient will lie prone with the foot dorsiflexion, and the probe will be placed vertically on the skin behind the lateral ankle and talus. During the scanning process of the aforementioned ligaments, apply appropriate pressure to the probe and observe the activity and tension of the ligaments during passive movements such as internal rotation, external rotation, and inversion of the foot. Pay attention to comparing with the healthy ligaments. Simultaneously observe the echo and continuity of the ligaments, whether there is hematoma in the surrounding soft tissues, and whether there is fluid accumulation in the joint cavity.

Anterior Talofibular Ligament (ATFL)

Place the affected limb slightly inward on the examination bed, fully exposing the lateral malleolus. First, place the probe on the outer side of the distal end of the fibula and move downwards until the tip of the fibula is reached. The distal end of the probe will be raised and moved forward to display the talus.

The Calcaneofibular Ligament (CFL)

Place the probe on the oblique coronal section of the lateral malleolus, with its upper edge flush with the tip of the lateral malleolus and slightly backward below. The long axis section shows a cord-like filamentous structure covering the outer

surface of the calcaneus, while the short axis section shows the CFL as an oval shape, sometimes resembling a free body related to the peroneal tendon in the joint. The lateral part of CFL runs deep in the peroneal tendon.

Incidence of Adverse Events

Researchers will record and evaluate every adverse event that occurs among participants. If serious adverse events occur, researchers need to immediately contact the chief investigator and ethics committee, and have them discuss and decide whether to remove the participant from the study. Participants who suffer harm due to research needs will be compensated. Common adverse events caused by acupuncture include fainting, stuck needle, bent needle, broken needle, and hematoma.

Quality Control and Data Management

Prior to the commencement of the study, a multidisciplinary research team, consisting of acupuncturists, orthopedic doctors, statisticians, and ultrasound imaging experts, reviewed, evaluated, and revised the test program. Members of this team were required to participate in a series of training sessions to ensure a thorough understanding of the research protocol and standard operating procedures. The researchers were asked to fill in the collected data as CRF according to the requirements of the research plan. After the study is completed, researchers need to submit all data to the data management center. The data management center needs to verify the authenticity and reliability of the data. If there is any data that does not match the true situation, researchers need to clarify it again.

Sample Size Calculation

Before undertaking this study, we performed a pilot study with a small sample size to determine the efficacy of EA for ALAS. The main outcome measure of this study is Kofoed score, and the sample size calculation is based on the comparison of the mean difference between three independent samples. According to the results of preliminary experiments, the mean and standard deviation of EA combined with surround needling group, sham EA group and ice combined with brake rest group were 88.24 ± 1.12, 83.57 ± 3.34, and 82.09 ± 8.45, respectively. Based on the formula, n_1 is 17 and n_2 is 18. The two results are relatively close, so n_2 is used as the sample size for each group, considering a 20% dropout rate, and ultimately 66 ALAS patients are needed.

Statistical Analysis

Continuous variables will be represented by mean ± standard deviation, with a 95% confidence interval for normal distribution and median and interquartile range for skewed distribution. Based on the collected data, rank sum test will be used for skewed distribution data, and analysis of variance will be used for normal distribution data. The effectiveness indicators and functional scores before acupuncture treatment (baseline), 3 weeks after treatment and 2 months after treatment will be recorded, respectively, and the index change values between the three groups and the baseline will be calculated after 3 weeks of treatment, 2 months after treatment, and the differences in the changes of the above indicators will be compared using the rank sum test or analysis of variance. Record safety events within 3 weeks of treatment and 2 months after the end of treatment. $P < 0.05$ will indicate statistical difference, and Statistical Package for Social Science (SPSS, version 22.0, IBM, USA) software will be used for statistical analysis in this study.

Discussion

ALAS is a prevalent disease associated with sports-related injuries. Symptomatic treatment is often adopted for ALAS in clinical practice, using methods such as analgesics combined with immobilization and ice compress. However, the gastrointestinal side effects of analgesics are significant, and some patients fail to achieve complete restoration of ankle joint ROM to its pre-injury state following treatment.

Traditional Chinese medicine (TCM) recognizes ALAS as the category of "tendon injury", which includes ligaments, tendons, fascia, and so on.[39] Acupuncture, known for its pain relief, anti-inflammatory, and anti-edema benefits, has long been used in China to treat ankle sprains. Acupoint selection often includes points near the ankle and the Ashi point, which targets the pain area. Some acupuncturists suggest choosing acupoints on the distal or healthy side to minimize

stimulation. However, clinical evidence supporting acupuncture's effectiveness on ALAS is currently insufficient and requires further investigation.

It is essential to investigate the potential therapeutic effects of acupuncture therapy on ankle sprains, as well as to assess whether the integration of medication, manipulation, and physical therapy can reduce the treatment duration and enhance efficacy. At present, clinical research on acupuncture treatment for ALAS is limited by a small overall sample size, a lack of standardized efficacy evaluation systems, and insufficient long-term follow-up of ALAS patients. Continued efforts are necessary to address these limitations and to facilitate the development and dissemination of more straightforward, effective, and innovative acupuncture treatments for ALAS.

This trial aims to provide stronger evidence to meet the needs of clinical practice by using MSKUS to quickly assess patients' musculoskeletal conditions, ensuring timely and appropriate treatment. MSKUS is chosen for its accuracy in evaluating ankle joint status and its cost-effectiveness, which improves patient compliance. As a convenient and economical examination method, MSKUS is gaining popularity in clinical settings and is valued by acupuncturists for its real-time diagnostic feedback.[40,41]

ALAS patients will be randomly divided into three groups: EA combined with surround needling group, sham EA group, and ice combined with brake rest group. The muscle and ligament conditions around the ankle joint will be evaluated before and after treatment, and during the follow-up period. This trial will use Kofoed score and MSKUS to make an evaluation, which can more timely and cost-effective assess the patient's ankle joint condition.

It is expected that this study will yield significant evidence within the field of acupuncture and lay a substantial foundation for future large-scale, multi-center clinical trials. Furthermore, the identification of an integrated EA modality for the treatment of ALAS is expected to be highly valuable in clinical practice. Some studies have indicated that kinesiology taping (KT) exerts a moderate stabilizing effect on the ankles of athletes participating in widely played contact sports who suffer from CAI.[42] This observation will indicate that future research could investigate the potential for improved therapeutic efficacy by integrating acupuncture with KT or other comprehensive treatment modalities in the management of ALAS or CAI.

Study Limitations

First, a notable limitation of this study is the enrollment of only 66 patients, constrained by financial limitations and a shortage of researchers. Despite this constraint, it is anticipated that the experimental study will yield valuable insights, thereby laying a groundwork for subsequent research endeavors. Second, in China, most people have experienced an acupuncture treatment. Although we will exclude patients who have received acupuncture treatment 4 weeks prior to the study and use the sham device, there is still high possibility that patients will distinguish the sham from verum acupuncture. Third, the fixed time of the brace is not strictly required, and patients can consult the doctor or make adjustments directly according to their own situation.

Trial Status

This study is currently in the recruitment phase. The first patient was randomised on 14 September 2024, and the study is expected to end by the end of 2025.

Data Sharing Statement

The data that support the findings of this study will be available from the corresponding author, Ding Tang, upon reasonable request.

Ethics and Dissemination

The entirety of the research procedures will adhere strictly to the ethical principles outlined in the "Declaration of Helsinki" (revised edition of October 19, 2013). The research protocol has secured endorsement from both the Institutional Review Board (IRB) and the Ethics Committee of the Third Affiliated Hospital, Zhejiang Chinese Medical University (permission number: ZSLL-ZN-2023-011-01). The results of the study will be disseminated in

a reputable, peer-reviewed academic journal. Patients will have the opportunity to access these results through secure channels, including the utilization of the WeChat platform or via telephone consultation.

Consent

Upon receipt of comprehensive information regarding the research procedures, potential risks, and their rights, each registered participant will be provided with a consent form.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare that they have no competing interests.

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