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STUDY PROTOCOL

Immediate Efficacy of Contralateral Acupuncture on SI3 Combined with Active Exercise for Acute Lumbar Sprains: Protocol for a Randomized Controlled Trial

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Purpose: Acute lumbar sprain (ALS) is a common clinical disease characterized by persistent intolerable low back pain and limitation of movement, and quick pain relief and restoration of mobility in a short time are the main needs of patients when they visit the clinic. This study aims to evaluate the immediate efficacy of contralateral acupuncture (CAT) on SI3 combined with active exercise in treating ALS.

Methods and Analysis: This study is a randomized controlled trial which will recruit 118 eligible participants aged 18 to 55 years with ALS at the Second Affiliated Hospital of Yunnan University of Chinese Medicine between March 2024 and December 2026. Participants will be randomly assigned to the acupuncture group or the sham-acupuncture group in a 1:1 ratio. The acupuncture group will receive a 10-minute acupuncture treatment combined with active exercise, while the sham-acupuncture group will receive a 10-minute sham acupuncture treatment combined with active exercise. Randomization will use a computer-generated sequence with allocation concealed in opaque envelopes. The primary outcome will be the pain visual analogue scale (VAS) scores after 10 minutes of treatment. Secondary outcomes will include the pain VAS scores at other time points (2, 4, 6, and 8 minutes post-treatment), the lumbar range of motion (ROM) scores at various time points, blinded assessment, the treatment effect expectancy scale, and the rescue analgesia rate. The analysis will follow the intention-to-treat principle. The primary outcome will be analyzed using ANCOVA, and secondary outcomes with repeated measures ANOVA. The rescue analgesia rate will be assessed using either the χ^2 test or Fisher's exact test.

Discussion: This study is the first randomized controlled trial to assess the immediate efficacy of CAT in combination with active exercise for ALS. This study will provide a simple, rapid, and effective treatment for the clinical management of ALS.

Keywords: acute lumbar sprain, immediate efficacy, contralateral acupuncture, active exercise, randomized controlled trial

Introduction

Acute lumbar sprain (ALS) is defined as an acute rupture of the muscles, fascia, ligaments, and other soft tissues of the lower back, often caused by sudden and excessive external forces. It is a common form of low back pain, accounting for about 12% of all low such cases.[1] Patients usually present with persistent intolerable low back pain and limitation of movement, which significantly affects their daily life and work.[2] Therefore, quick pain relief and restoration of mobility in a short time are the main needs of patients when they visit the clinic.

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The American College of Physicians Clinical Practice Guidelines recommends nonsteroidal anti-inflammatory drugs (NSAIDs) as the first-line treatment for pain in ALS patients.[3,4] Previous studies have found that patients begin to experience pain relief on average about 30 minutes after taking NSAIDs, with significant pain relief averaging about two and a half hours.[5–7] This indicates that even after taking the medication, patients still need to tolerate the pain for a prolonged period of time. Additionally, some patients report that their pain persists despite the use of medications.[8,9] Furthermore, the use of NSAIDs may have side effects on the digestive and cardiovascular systems.[10,11] Thus, complementary alternative therapies are considered advantageous treatments for improving ALS symptoms.[12] Recent studies have also highlighted the benefits of manual therapy and exercise in reducing pain and disability in patients with low back pain.[13,14]

Acupuncture, a traditional non-pharmacologic therapy, has potential advantages in the treatment of acute pain disorders.[15–17] Clinical studies have indicated that acupuncture can alleviate pain and enhance mobility in ALS patients.[18–20] Contralateral acupuncture (CAT) is a traditional acupuncture technique that has been used in China for more than 2000 years. It is characterized by selecting acupoints on the right (healthy side) for needling when the left (affected side) is diseased.[21] This method is particularly effective in treating acute unilateral pain, such as acute migraine and shoulder pain.[22,23] ALS often presents as unilateral low back pain, which is well-suited for CAT treatment.[24] Additionally, exercise is a well-established adjunct therapy for acute mobility disorders, contributing to pain reduction and the improvement or restoration of functional activities.[25] A recent study suggests that combining CAT with active exercise improves pain and dysfunction in patients with ALS in a short period, but with limitations such as small sample size and insufficient blinding.[26] Therefore, the immediate efficacy of this combined therapy for ALS remains unclear, necessitating further validation.

The objective of this study is to evaluate the immediate efficacy of CAT on SI3 (Houxi acupoint) combined with active exercise in treating ALS. The findings of this research will provide high-quality evidence supporting the application of this combined therapy for ALS.

Methods and Analysis

Study Design and Setting

The study protocol is designed according to the standard protocol item: Recommendations for Interventional Trials 2013 Statement (SPIRIT 2013) (Supplementary Material 1) and followed the principles of the Declaration of Helsinki.[27] This study has been approved by the Ethics Committee of the Second Affiliated Hospital of Yunnan University of Traditional Chinese Medicine (2023–007) and registered with the China Clinical Trial Registry (ChiCTR2400079752).

This study is a randomized controlled trial which will recruit 118 eligible participants aged 18 to 55 years with ALS at the Second Affiliated Hospital of Yunnan University of Chinese Medicine between March 2024 and December 2026. Participants will be randomly assigned to the acupuncture group or the sham-acupuncture group in a 1:1 ratio. All participants will be given a 10-minute treatment. The flowchart is shown in Figure 1. The schedule of enrollment, intervention, and assessment is detailed in Table 1.

Participants

Recruitment of participants will mainly be through posting posters in the orthopaedic and acupuncture outpatient clinics of the Second Affiliated Hospital of Yunnan University of Chinese Medicine and in the Kunming community. Participants will be diagnosed by a licensed orthopaedic physician with at least five years of clinical experience, ensuring accurate diagnosis and eligibility for the study. Eligible participants will be required to provide written informed consent (Supplementary Material 2) before the randomization group. Participants will retain the right to withdraw from the study at any time.

Diagnostic Criteria

Refer to the diagnostic criteria for ALS as outlined in the "Clinical Diagnosis and Treatment Guidelines: Orthopedics" published by the Chinese Medical Association:

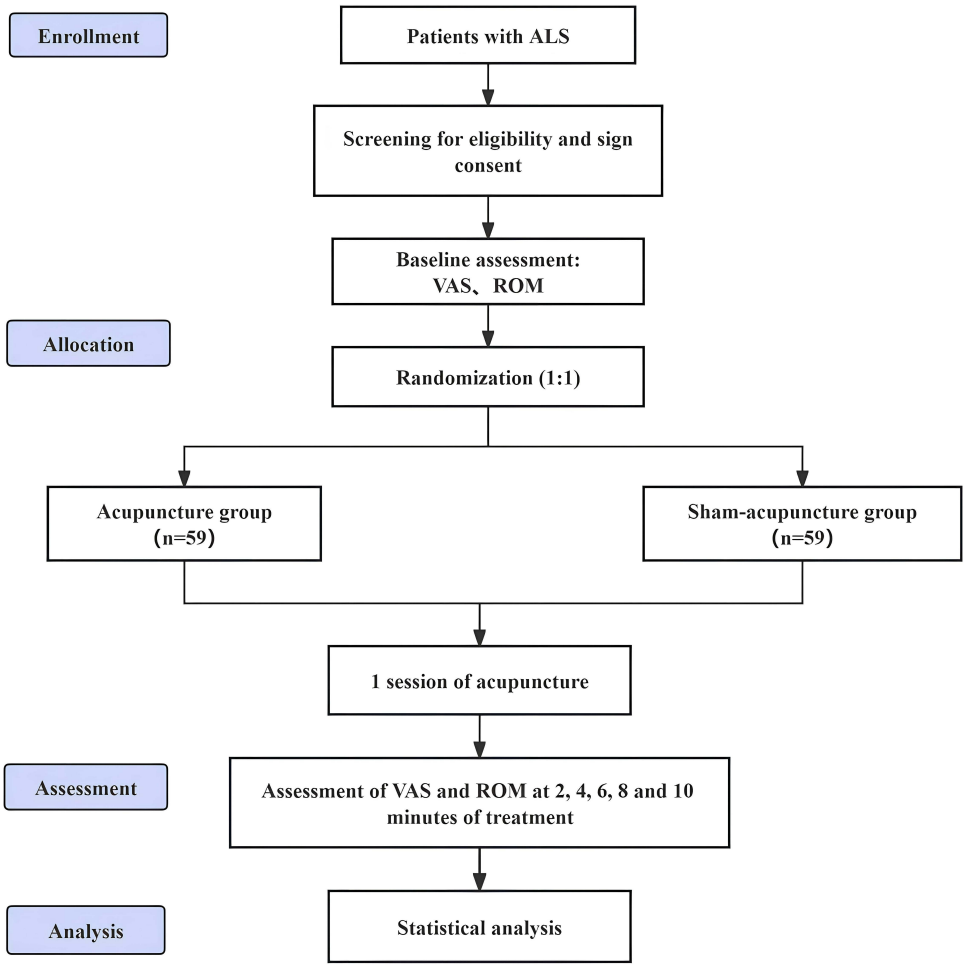

Figure 1 Flow diagram.

1. History of ALS;
2. Lumbar deformity, lumbar muscle spasm, and activity limitation;
3. Obvious fixed pressure pain at the injury site;
4. Lumbar spine X-ray without obvious positive features.[28]

Table 1 Study Schedule for Data Measurements

Items	Baseline Period (Minutes)	Treatment Period (Minutes)				
STUDY PERIOD						
TIMEPOINT	0	2	4	6	8	10
ENROLMENT:						
Eligibility screen	×					
Informed consent	×					
Inclusion/exclusion criteria	×					
Randomization	×					

(*Continued*)

Table 1 (Continued).

Items	Baseline Period (Minutes)	Treatment Period (Minutes)				
INTERVENTIONS:						
Acupuncture group		×	×	×	×	×
Sham-acupuncture group		×	×	×	×	×
ASSESSMENTS:						
VAS	×	×	×	×	×	×
ROM	×	×	×	×	×	×
Treatment effect expectancy	×					
Blind evaluation						×
Rescue analgesia rate						×
Safety evaluation						×
Compliance evaluation						×
PARTICIPANTS SAFETY:						
AEs		×	×	×	×	×

Abbreviations: VAS, visual analogue scale; ROM, range of motion; AEs, adverse events.

Inclusion Criteria

Participants will be eligible if they meet all the following criteria:

1. Conform to the diagnostic criteria of ALS;
2. Unilateral low back pain, age 18–55 years old, male or female;
3. Duration of the disease ≤ 3 days;
4. Moderate to severe low back pain, with a visual analogue scale (VAS) between 4 and 8;
5. Signed the informed consent form and voluntarily participated in this study.

Exclusion Criteria

Participants will be excluded with any of the following:

1. Presence of concurrent lumbar spondylolisthesis, tuberculosis, tumors, fractures, or other spinal pathologies;
2. Lumbar pain resulting from urinary system diseases, gynecological conditions or acute and chronic infections;
3. Coexistence of severe cardiovascular, cerebrovascular, hepatic, renal, or coagulation system disorders;
4. Combined serious mental illness or intellectual disability, rendering them unable to complete the questionnaire;
5. Pregnant or breastfeeding women;
6. Used other methods of pain relief within the past 6 hours.

Randomization and Blinding

Participants will be randomly assigned to the acupuncture group and the sham-acupuncture group in a 1:1 ratio. To minimize selection bias, an independent statistician will use SPSS 28.0 (IBM, Chicago, IL, license code: f56b44b8d8e3562ad8a2) to generate random numbers. These numbers will be enclosed in opaque envelopes. Participants will choose one of these envelopes after agreeing to the principle of random allocation, which will determine their group assignment and the

corresponding intervention method. To further ensure research rigour, treatments will be administered in separate rooms to prevent participants from sharing information. Participants, outcome assessors, and statistical analysts will be blinded to group assignments. Although acupuncturists will be aware of the treatment allocations, they will not participate in the subsequent outcome assessment or data analysis.

Interventions

The interventions in this study will adhere to the Comprehensive Standards for Trial Reporting and the Standards for Reporting Interventions in Acupuncture Clinical Trials.[29,30] All participants will receive a single acupuncture session at the healthy side SI3 (on the back of the hand, in the depression between the red and white meatus proximal to the ulnar side of the 5th metacarpophalangeal joint).[31] The location of SI3 is presented in Figure 2. Treatments in this study will be conducted by licensed acupuncturists with at least 5 years of experience. All acupuncturists will receive training to ensure that they are fully familiar with the treatment procedure at the beginning of the trial.

Appliance Selection

Park Sham Acupuncture Device (PSD) (Figure 3): This device includes a transparent catheter (Φ4×20mm), double-sided tape (Φ1×15mm), and an opaque plastic base, It is manufactured by Suzhou Medical Supplies Factory Limited, with batch number: 210401.

Acupuncture Needles: Huatuo brand disposable acupuncture needles will be used, produced by Suzhou Medical Supplies Factory Limited. The manufacturer holds license number Su Food and Drug Supervision and Mechanical Production Xu 2001–0020, and registration certificate number Su Food and Drug Supervision and Mechanical (Quasi) 24 No. 201622770970, with the specification of 0.25×40mm.

Blunt Needles: 0.25×40mm retractable stainless steel blunt-tipped needles, lot number 200304, manufactured by Suzhou Medical Supplies Limited, will be selected.

Protractor: Protractors made of stainless steel, measuring 90×155mm, produced by the company in Huzhou, Zhejiang, China, will be utilized.

Operation

Before the treatment, participants take a seated position, exposing the acupoint, and the acupuncturist will sterilize the surrounding skin.

Acupuncture Group

A PSD and an acupuncture needle will be selected. The tape on the skin side of the PSD will be removed, and then the needle will be inserted into the PSD with the needle tip exposed. Subsequently, the needle will be affixed to the SI3 on the healthy side

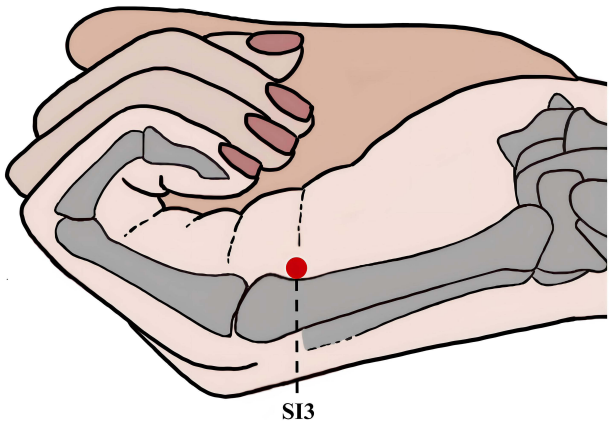

Figure 2 Location of acupoint.

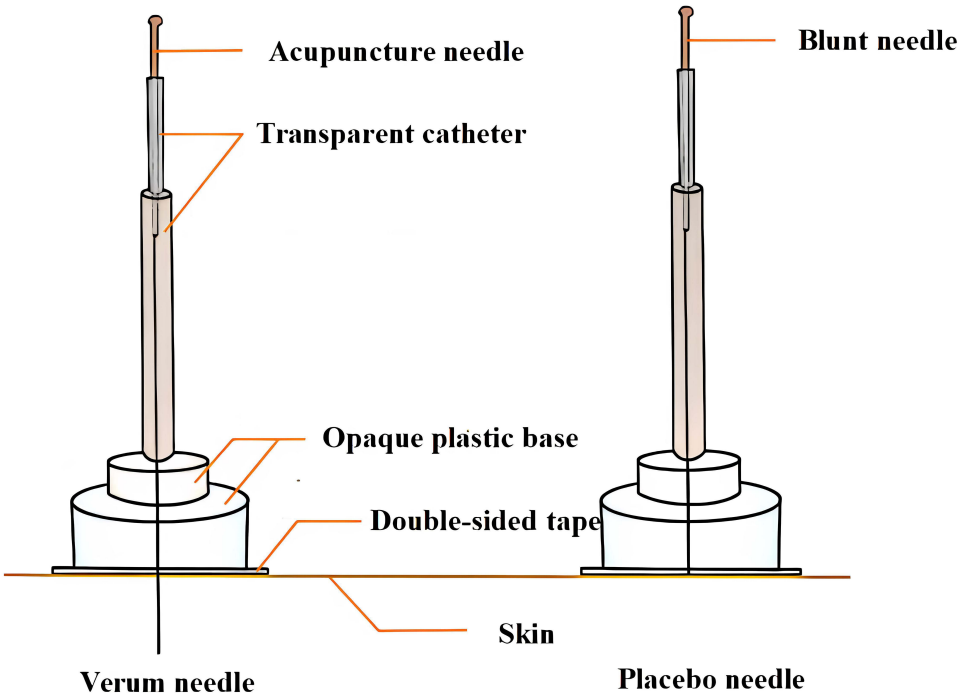

Figure 3 Park Sham Acupuncture Device.

and inserted perpendicularly towards the Hegu (LI 4) point to a depth of 20 to 30 mm.[32] Large amplitude twisting techniques (180° to 360°) will be employed to elicit the "Deqi" sensation.[33,34] Once achieved, the participant will be asked to stand. The doctor will stand behind the participant and support the participant's lower back with both hands. Then, the participant will be instructed to perform slow movements including forward flexion, backward extension, lateral flexion, and rotation within their pain-tolerable range, as shown in Figure 4. The range and speed of these movements will increase gradually as pain decreases.

Participants in the acupuncture group will receive a single 10-minute session of acupuncture treatment.

Sham-Acupuncture Group

A PSD and a blunt needle will be used. The tape on the skin side of the PSD will be removed, and a retractable blunt needle will be inserted. The blunt needle will not pierce the skin, but the participant will feel a pinprick sensation. The subsequent steps will be the same as in the acupuncture group.

Participants in the sham-acupuncture group will receive a 10-minute session of sham-acupuncture treatment.

Emergency Treatment

In cases where a participant's low back pain persists or worsens during the treatment, the intervention will be immediately discontinued, and emergency measures will be implemented. This includes administering NSAIDs and transporting participants to the emergency department for further evaluation and treatment if necessary. In addition, participants in the sham-acupuncture group whose symptom do not relieve will be offered real acupuncture treatment or other emergency interventions.

Outcomes

Primary Outcome

The primary outcome will be the pain VAS scores after 10 minutes of treatment.

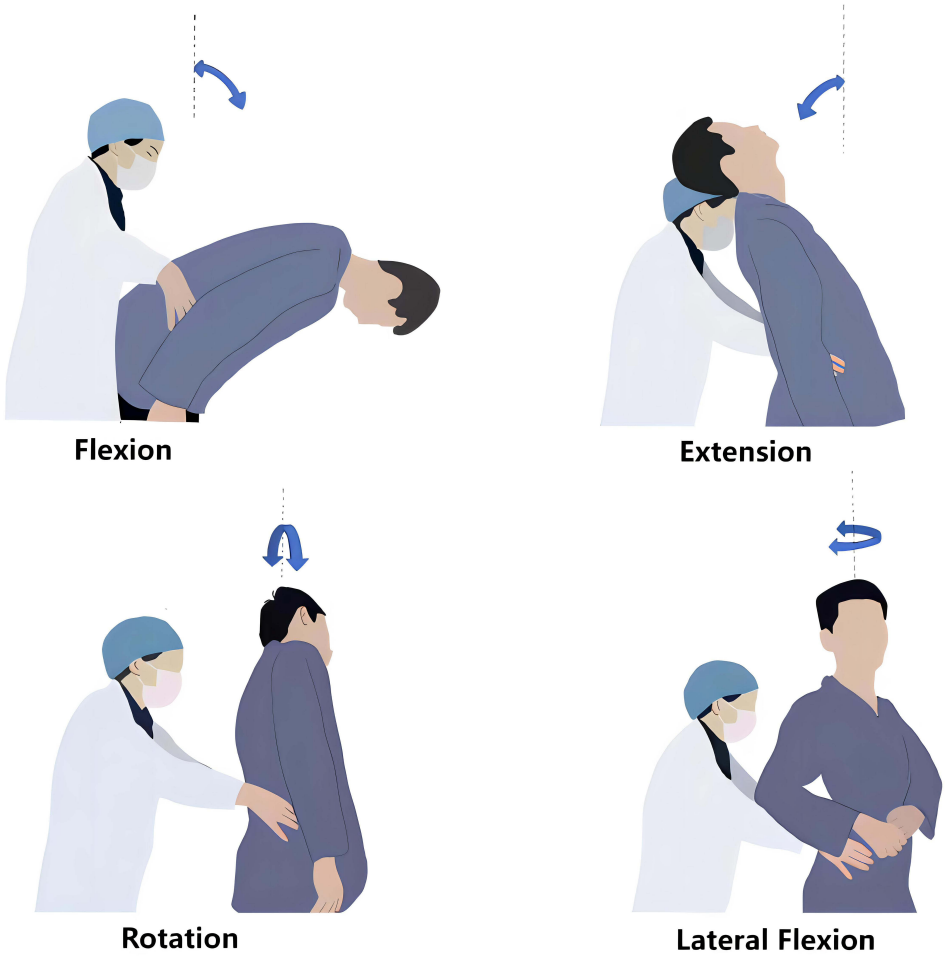

Figure 4 Lumbar exercises during acupuncture.

Secondary Outcomes

Secondary outcomes will include the pain VAS scores at other time points (2, 4, 6, and 8 minutes post-treatment), the lumbar range of motion (ROM) scores at various time points, blinded assessment, the treatment effect expectancy scale, and the rescue analgesia rate.

Outcome Measurements

The VAS is a widely-recognized tool for evaluating pain, with scores ranging from 0 (no pain) to 10 (severe pain). Higher scores indicate more severe pain.[35] The assessment will be conducted six times: at baseline, and 2, 4, 6, 8, and 10 minutes during the treatment process (Supplementary Material 3).

The ROM is a fundamental indicator of lumbar function. It can be quantified using a 5-point Likert scale. The scoring is as follows: A score of 0 is given when the participant can bend forward freely and touch the floor with the fingertips. A score of 1 is given if the participant can bend sufficiently to touch the knees with the hands. Bending beyond 70 degrees scores 2 points. A slight bend is scored as 3 points. If the participant is completely unable to bend forward, they receive 4 points. If the lumbar spine is unable to bend forwards, but instead shows reverse extension, this is scored 5.[36] The scale will be measured at the same intervals as the VAS (Supplementary Material 4).

The treatment effect expectation scale will be employed to assess anticipated treatment outcomes before the commencement of therapy (Supplementary Material 5).

To assess the success of blinding, patients will be asked at the end of their treatment if they believe they received true acupuncture therapy. Furthermore, they will be instructed to rate their certainty about their answer on a scale from 0 to 10, where 0 indicates complete uncertainty and 10 signifies absolute certainty (Supplementary Material 6).

The percentage of patients requiring additional analgesic medication will be counted at the end of the acupuncture treatment (Supplementary Material 7).

Sample Size

This study is designed as a superiority trial to assess whether acupuncture combined with exercise is more effective than sham-acupuncture combined with exercise in treating ALS. A previous clinical study has shown that acupuncture combined with exercise and sham-acupuncture combined with exercise in treating ALS for 10 minutes decreased VAS scores by 4.6±1.0 and 2.7±1.0, respectively.[37] Based on this finding, we hypothesize that the change in VAS scores after 10 minutes of treatment will be 4.6±1.0 in the acupuncture group and 2.7±1.0 in the sham-acupuncture group, with α=0.025 (unilateral), β=0.1, Δ=1.3, and K=1.[38] The sample size was calculated based on the following formula:

$$n_c = \frac{\left(Z_{1-\alpha} + Z_{1-\beta}\right)^2 \sigma^2 \left(1 + \frac{1}{K}\right)}{\left(\mu_T - \mu_C - \Delta\right)^2}$$

It was calculated that a minimum of 59 patients were needed in each group.[39] Since only one treatment will be done, patient dropout will not be considered. A total of 118 patients will be recruited.

Statistical Analysis

SPSS 28.0 will be used to analyze all data in this study. When analyzing demographic characteristics, the normality of distribution will dictate the use of either independent samples *t*-tests or Wilcoxon rank-sum tests to evaluate continuous variables between two groups. For categorical variables in demographic characteristics, χ^2 test or Fisher's exact tests will be employed. Covariates such as age, gender, and baseline pain levels will be controlled through randomization. To control for potential confounding factors, significant differences in demographic characteristics emerge, these will be incorporated as covariates in subsequent efficacy analyses. Levene's test for equality of variances will be used to assess the homogeneity of variances. The change in pain VAS score from baseline to 10 minutes into treatment will be analyzed using analysis of covariance (ANCOVA), with the treatment modality (acupuncture or sham-acupuncture) as the factor and baseline pain VAS score as the covariate. Differences in secondary outcomes at various time points will be examined using repeated measures analysis of variance (ANOVA). If these analyses do not meet the homogeneity of variance assumption, Welch's ANOVA will be used. Evaluation of rescue analgesia rate using χ^2 test or Fisher's exact test. Adhering to the intention-to-treat (ITT) principle, our analyses will encompass all participants who received randomized treatment.

Data Management and Confidentiality

All raw clinical data will be detailed in a Case Report Form (CRF) and retained for at least five years after publication. The accuracy of these data will be monitored by two clinical research assistants. To protect the privacy of the subjects, only the outcome assessors will have access to the CRFs. The Ethics Committee will periodically review trial progress and CRF integrity, and it reserves the right to modify or terminate the trial. There is no conflict of interest between this committee and the research project. Throughout the study, all personal information relating to participants will be kept strictly confidential. Under no circumstances will this information be disclosed to any third party, individual or organization without the consent of the participant.

Adverse Events Report

Any adverse events (AEs) observed during treatment will be fully evaluated and documented on a CRF. These AEs may include acupuncture-related events like severe localized pain, subcutaneous congestion, hematoma, localized infections, syncope, nausea, and unrelated symptoms such as cough or headache. All AEs will be treated promptly.

Discussion

ALS is a common acute pain disease characterized by intolerable pain and limitation of movement. Patients are urgently needing rapid relief of their symptoms. The result of this study is expected to provide a rapid, simple, and effective alternative treatment for ALS.

In clinical practice, the symptoms of ALS usually present unilaterally. Therefore, we opted for contralateral acupuncture, which is particularly effective in treating disorders characterized by unilateral pain.[40,41] The main pathological features of ALS include aseptic inflammation and lumbar muscle spasms.[42] Contemporary studies have shown that CAT is effective in reducing aseptic inflammation and relieving muscle spasms on the affected side, but further research is needed.[43,44] Moreover, ALS is usually accompanied by subluxation of the small intervertebral joints and embedding of the surrounding joint capsule, which restricts lumbar mobility.[45] During acupuncture, combined with exercise can promote the repositioning of slightly displaced lumbar intervertebral small joints and fascia, correct endogenous posterior joint disorders and imbalance of external motor structures, and restore normal motor function.[46]

When determining the timing for observations, we noted that previous studies on acute pain have typically involved treatment periods of 30 minutes or longer.[47,48] However, recent evidence suggests that treatment of ALS can achieve significant efficacy in shorter periods (10 minutes).[49] Considering that patients with ALS have severe pain and need immediate pain relief in the shortest possible time, our study adopted a 10-minute observation period, with assessments conducted every two minutes, to document in detail the immediate efficacy of the treatment. In addition, the short duration of treatment allowed us to use conventional medications promptly when acupuncture did not provide adequate pain relief. Considering that the operation needs to be simple, effective, and repeatable, and to minimize the discomfort of the patients during treatment, only one acupoint, SI3, is selected for treatment in this study. In Chinese medicine, the SI3 is esteemed as a critical point for treating low back pain and is extensively utilized in clinical practices for ALS.[37,50] For measurement tools, we chose the VAS and ROM due to their relative objectivity and sensitivity, as well as the clarity and intuitive nature of the measurements.[51,52] These tools facilitate rapid assessment and are directly related to the patient's main symptoms, ensuring the validity and reliability of the results.[37]

Existing research indicates that sham-acupuncture, such as non-acupoint or superficial needling, can produce effective treatment effects.[53,54] To reduce the impact of these non-specific effects, this study will use non-penetrating blunt needles for the control group.[55] During treatment sessions, acupuncturists will ensure that these blunt needles make contact with the skin, inducing a mild tingling sensation. This approach aims to minimize differences in needling sensations between groups and to enhance the blinding effect of the trial. Previous studies have suggested that patients' expectations of treatment efficacy may influence the outcomes of low back pain treatment, but no definitive conclusions have been reached.[56,57] Therefore, we included an efficacy expectation scale to eliminate the potential influence of patients' psychological expectations on the outcomes of acupuncture treatment.

This study is the first randomized controlled trial to assess the immediate efficacy of CAT in combination with active exercise for ALS. This study will provide a simple, rapid, and effective treatment for the clinical management of ALS. This study primarily observes the efficacy of acupuncture treatment, with medication administered only when acupuncture is not effective. This approach not only highlights the advantages of acupuncture, which has the potential to reduce the use of analgesic medications in the clinic, but also provides a basis for considering acupuncture as an initial treatment option for acute pain. However, some limitations of the study should also be recognized. Firstly, because of the specific characteristics of the acupuncture operation, the acupuncturists could not be blinded, which may affect the objectivity of the treatment results. To mitigate this bias, acupuncturists will not participate in outcome assessment or data analysis. Secondly, this is a single-centre study and its reproducibility needs to be further investigated. Thirdly, there is no follow-up in this study, thus there is a lack of knowledge about the long-term effects and durability of the treatment. These issues will be comprehensively explored in future studies.

In summary, this study aims to assess the immediate efficacy of CAT combined with active exercise for ALS. For researchers, this study will provide high-quality evidence on the immediate effects of this combined therapy approach. For clinicians and patients, the findings offer a simple and rapid alternative treatment protocol for managing ALS. The treatment duration of this study is only 10 minutes and the results will contribute significantly to understanding the efficacy of acupuncture in acute pain relief. Furthermore, the results of this study may also provide evidence to support the potential of acupuncture to reduce drug dependence.

Abbreviations

ASL, acute lumbar sprain; VAS, visual analogue scale; ROM, range of motion; ITT, intention-to-treat; AEs, adverse events; CRF, case report form; PSD, Park Sham Acupuncture Device.

Trial Status

The trial is set to initiate recruitment and treatment on 1 March 2024 and is anticipated to be completed by 22 December 2026.

Ethics and Dissemination

This study was approved ethically by the Ethics Committee of the Second Affiliated Hospital of Yunnan University of Chinese Medicine on December 30, 2023, under document number 2023-007. It follows the principles of the Declaration of Helsinki. The results of the study will be published in a peer-reviewed journal and presented at a conference.

Patient Consent for Publication

Obtained.

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 report no conflicts of interest in this work.

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