Trials

STUDY PROTOCOL

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Effect of extracorporeal shock wave combined with autologous platelet-rich plasma injection on rotator cuff calcific tendinitis: study protocol for a randomized controlled trial

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Abstract

Background Rotator cuff calcific tendinitis (RCCT) is a common shoulder disease whose main symptoms include shoulder pain, limited mobility, and calcification deposits in the shoulder. Traditional treatment methods have certain limitations, so finding new treatment methods has become the focus of research. Extracorporeal shock wave (ESW) and platelet-rich plasma (PRP) treatments have attracted much attention due to their non-invasive and tissue repair-promoting properties; however, the efficacy of their combined treatment in RCCT remains unclear.

Methods This study is designed as a single-center, assessment-blind, randomized controlled clinical trial with three parallel groups. Sixty subjects will be recruited and randomly divided into the ESW group, PRP group, and ESW combined with PRP group, in a 1:1:1 ratio. The entire intervention period is 4 weeks, and the follow-up period is 4 weeks. Outcomes will be measured at baseline (T0), after 1 week of intervention (T1), after 2 weeks of intervention (T2), after 4 weeks of intervention (T3), and after an additional 4 weeks of follow-up period (T4). The primary endpoint is the VAS score. Secondary endpoints are ASES, CMS, UCLA, and the location and size of calcified areas.

Discussion This study aims to evaluate the efficacy of ESW therapy combined with PRP in treating RCCT. We compare the effects of single and combined treatments to explore their impact on disease symptoms, functional improvement, and calcification regression. This provides a scientific basis for identifying more effective treatment options.

Trial registration ClinicalTrials.gov NCT06372600. Registered on April 17, 2024; version 1.

Keywords Extracorporeal shock wave, Platelet-rich plasma, Rotator cuff, Calcific tendinitis, Protocol, Randomized controlled trial

Introduction

Background and rationale {6a}

Rotator cuff calcific tendinitis (RCCT) is a prevalent shoulder disease, primarily characterized by calcific deposits in the rotator cuff tendons, notably the subacromial tendon [1]. Most studies have found that the incidence rate is 2.7–22% [2–4]. The epidemiological characteristics of this disease indicate that it is relatively common in adults, with a higher incidence in women compared with men, especially in those aged 40 to

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60 years [5, 6]. Bilateral involvement is common in RCCT and is generally not associated with manual labor [7]. Although its exact cause is not fully understood, research suggests that tendon degeneration, poor blood supply, and chronic inflammation may be key factors leading to tendon calcification [8]. The main clinical manifestations of RCCT are shoulder pain and limited movement, and these symptoms may lead to sleep disturbance, reduced work efficiency, and a significant decrease in quality of life [9, 10]. Furthermore, the natural history of the disease may involve multiple stages, from the formation of calcifications to their eventual natural resorption, but this process may last for years and patients may suffer from ongoing pain and discomfort during this period [11, 12]. The main complications of RCCT include pain, adhesive capsulitis, rotator cuff tears, greater trochanter osteolysis, and ossifying tendinitis [3]. Therefore, timely RCCT treatment is very important to relieve pain, prevent complications, and help restore shoulder function.

Although RCCT is relatively common clinically, its treatment remains a challenging issue. Currently, there are various treatments for RCCT, with traditional treatments including conservative treatment [13], physical therapy [14], drug therapy, and in extreme cases, surgical intervention [15]. However, these methods do not always achieve the desired results in a short period, and the high cost and many complications of surgery can be prohibitive for some patients. According to Hurt and Baker, non-surgical treatment can relieve symptoms in approximately 90% of patients [16]. With the continuous advancement of medical technology, more and more non-invasive treatments have been introduced into the treatment field of RCCT [17].

ESW treatment is widely used due to its non-invasive nature and low risk of complications [18, 19]. Its functions mainly include the following aspects: biomechanical effect. The mechanical shock wave generated by ESW can be transmitted to the patient's tissue to produce biomechanical effects. This mechanical stimulation may help break up and break down the calcified material in the calcified area of the rotator cuff, promoting its absorption and drainage [20]. Anti-inflammatory, ESW may work by reducing the inflammatory response. Mechanical shock waves may stimulate anti-inflammatory responses in organisms, reduce local inflammation levels, and help reduce patients' pain and discomfort [21]. Blood flow improves, and ESW may improve local blood circulation, increase the supply of oxygen and nutrients, and accelerate the repair and recovery of damaged tissues [22]. Neuromodulation, ESW may reduce patients' pain perception by affecting the nervous system. This may be related to the impact of mechanical stimulation on nerve fibers and interference with pain transmission pathways [23]. Fibrosis and repair, ESW may stimulate fibrosis and repair processes in damaged tissues. Mechanical stimulation may activate fibroblasts, promote collagen production, and help repair damaged tendon tissue [24]. Biological effects at the cellular level, ESW may produce biological effects at the cellular level, including promoting cell proliferation and increasing the release of growth factors, thus contributing to tissue repair and regeneration [25, 26]. In RCCT patients, ESW helps break down calcification deposits within tendons by delivering high-energy sound waves and may promote local blood circulation and tissue repair [27].

In recent years, autologous platelet-rich plasma (PRP) therapy has shown potential in promoting tissue repair and alleviating inflammation. PRP is a method of obtaining platelet-rich plasma by extracting and processing the patient's blood [28]. This platelet-rich plasma can be used for orthopedic surgery, cardiac surgery, sports injuries, plastic surgery, gynecology, urology, and cosmetic purposes [29]. PRP therapy has become a hot topic in the treatment of joint diseases in recent years. Its advantage is that it can provide a large number of growth factors in a short period, accelerate cell proliferation and the formation of new blood vessels, help improve the microenvironment of local tissues, and improve self-healing capabilities [30, 31]. PRP contains a large amount of growth factors and cytokines and can be injected directly into damaged tendon tissue to promote cell proliferation and tissue regeneration. Healing time is prolonged in chronic tendinopathy because the tendon is relatively less vascular and the local blood flow to the muscle is less regulated. Therefore, the use of platelet-rich plasma (PRP) and proliferative therapy has recently become a treatment option for rotator cuff tendinopathy [32, 33]. Although the effectiveness of PRP in the treatment of tendon disorders is still under investigation, preliminary evidence suggests its potential value in the treatment of RCCT [34–36].

Objectives {7}

This study aims to evaluate the efficacy of ESW combined with PRP in the treatment of RCCT. We hypothesize that this combined treatment strategy will not only effectively break down calcific deposits within the tendon but also facilitate the natural repair process of the tissue, thereby improving the patient's pain symptoms and functional status. By conducting this study, we anticipate providing more efficacious clinical solutions for the treatment of RCCT in the future.

Trial design {8}

This study is an exploratory, single-center, assessment-blind, randomized controlled clinical trial with three

parallel groups: ESW group, PRP group, and ESW combined with PRP group. Sixty subjects will be randomly assigned in a 1:1:1 ratio.

Methods: participants, interventions, and outcomes

Study setting {9}

Study population recruitment

The study population will be recruited from the Department of Rehabilitation Medicine, Affiliated Hospital of Chengdu Sport University, Chengdu, China. The inclusion and exclusion criteria for the study population will be as follows.

Eligibility criteria {10}

Inclusion criteria

(1) Comply with RCCT diagnostic criteria [6], aged between 40 and 60 years old.
(2) Persistent pain in the affected shoulder, obvious tenderness under the acromion and rotator cuff, examined by X-ray, CT, and MRI, it shows that there are one or more round-like high-density calcium salt deposits near the greater tuberosity of the humerus.
(3) All are diagnosed for the first time.
(4) Complaints of severe pain in the shoulder joint, obvious pain at night, non-steroidal anti-inflammatory drugs, and other conservative treatments are not effective.
(5) Agree to sign an informed consent form.

Exclusion criteria

(1) Combined with rotator cuff trauma, long head of biceps tendinitis, and other shoulder joint diseases.
(2) History of shoulder joint surgery.
(3) Shoulder joints with internal fixation.
(4) Shoulder joints combined with infections and tumors and other pathological changes.
(5) Combined with severe heart, liver, and renal insufficiency.
(6) Do not agree to participate in the study or fail to sign the informed consent form.

This study will be conducted at the Department of Rehabilitation Medicine, Affiliated Hospital of Chengdu Sport University (Chengdu, China). The research design flow chart is shown in Fig. 1. The research protocol follows the Standard Protocol Items: Recommendations for Intervention Trials 2013 [37]. The study schedule is shown in Fig. 2.

Who will take informed consent? {26a}

The fully trained designated researchers (WXF, JSY, CJH, XXL) who are present on-site will be responsible for obtaining informed consent from participants.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

This trial does not involve collecting biological specimens for storage.

Interventions

Explanation for the choice of comparators {6b}

The decision to undertake a comparative study of PRP and ESW combined with PRP stems from the complementary advantages of both treatments. PRP's rich growth factors promote healing, while ESW's biological effects activate cellular activity. Their synergy enhances therapeutic outcomes, accelerates tissue repair, and may offer safer, more effective alternatives to surgical interventions for orthopedic conditions like non-unions and fracture healing.

Intervention description {11a}

The ESW group will receive ESW treatment, the PRP group will undergo PRP injection, and the ESW combined with the PRP group will be administered ESW treatment in conjunction with PRP injection. Among these groups, the intervention site for ESW will be targeted at the calcification pain point on the shoulder. For each session, 2 to 3 points will be selected, and a coupling agent will be applied to enable the treatment head to conform to the skin, enabling both longitudinal and transverse treatment. The frequency will be preset at 4 to 8 Hz, with a probe length of 15 mm, an intensity of 1.5 mJ/mm^2, and each treatment point will receive 2000 to 2500 pulses. The handheld pressure will be adjusted to medium to high levels, culminating in a total of 6 treatment sessions. For patients experiencing vague pain points or regional pain, the treatment will focus on the supraspinatus or infraspinatus tendon, in conjunction with the area of most severe pain.

The procedure for PRP injection will involve the following: (1) Blood sample collection: Samples will be drawn from the patient's blood, typically via venipuncture. (2) Platelet separation: Platelets in the blood will be concentrated through centrifugation and other methods to produce PRP. (3) PRP injection: The prepared PRP will be injected into the rotator cuff calcification lesion area under ultrasound guidance, aiming to enhance tissue repair and exert anti-inflammatory effects.

The ESW sessions will last for 20 min each. Following the ESW treatment, the combination group will rest for

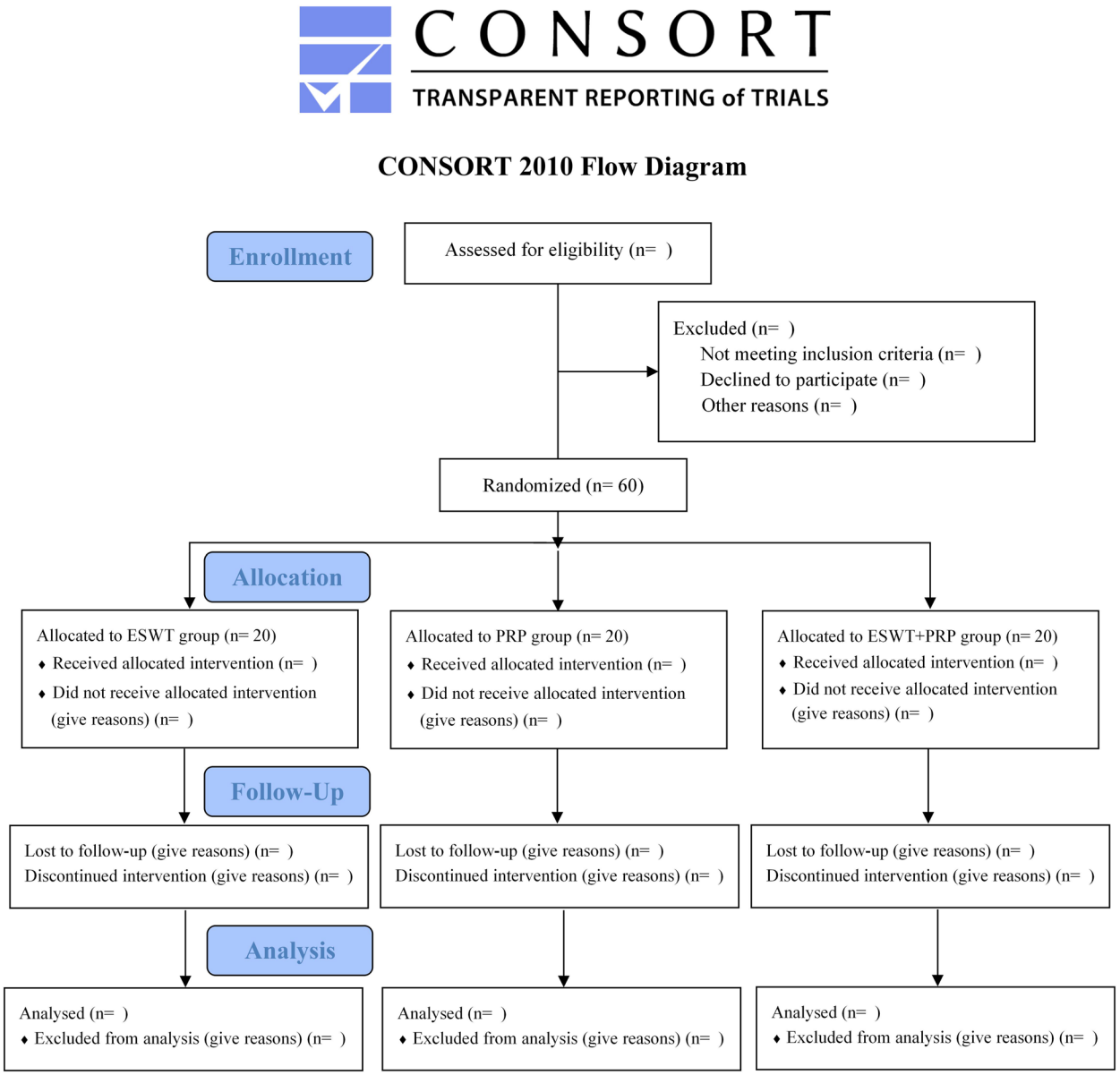

Fig. 1 Study design diagram

half an hour before proceeding with the PRP injection. The treatment frequency for all groups mentioned will be once weekly for 4 consecutive weeks.

Criteria for discontinuing or modifying allocated interventions {11b}

Interventions will be discontinued if:

1. Worsening symptoms or discomfort after treatment.
2. Serious adverse reactions or complications.
3. Development of other serious diseases requiring emergency surgery.
4. Poor compliance with intervention.
5. Refusal to continue the study.
6. And if any other unforeseen serious side effects occur, the intervention will also be terminated.

Strategies to improve adherence to interventions {11c}

At the end of each weekly treatment session, regular follow-up phone calls and appointment reminders will be employed as strategies to enhance patient compliance. During these interactions, patients' treatment experiences will be discussed, and they will be reminded of

	STUDY PERIOD					
	Enrolment	Baseline assessment	Post-treatment assessment			Follow-up
TIMEPOINT	$-t_1$	0	T_{1w}	T_{2w}	T_{4w}	T_{8w}
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Ethical approval and trail registration	X					
Allocation		X				
INTERVENTIONS:						
ESWT group			♦—	—	—	—♦
PRP group			♦—	—	—	—♦
ESWT+PRP group			♦—	—	—	—♦
ASSESSMENTS:						
Basic characteristics information	X					
VAS			X	X	X	X
ASES			X	X	X	X
UCLA			X	X	X	X
Location and size of calcification			X	X	X	X

Fig. 2 Flow chart of the intervention plan of the study

the importance of adhering to the prescribed treatment regimen.

Relevant concomitant care permitted or prohibited during the trial {11d}

Implementing will not require alteration to usual care pathways (including the use of any medication) and these will continue for both trial arms.

Provisions for post-trial care {30}

Free treatment will be provided for any intervention-related hazards such as needle infections associated with PRP injections.

Outcomes {12}

Outcome measures

Primary outcomes The primary outcome measure will be the patient's shoulder pain after treatment, using the Visual Analog Scale (VAS), a common assessment tool used to quantify pain levels. It is assessed by asking patients to mark on a straight line the location of their current pain sensation. VAS is a simple yet effective tool for capturing and recording a patient's subjective assessment of pain sensation.

Secondary outcomes The secondary evaluation results are as follows:

American Shoulder and Elbow Surgeon's Form, ASES

The American Shoulder and Elbow Surgeons (ASES) standardized shoulder assessment form is a widely used tool in the orthopedic field to evaluate shoulder function. It is designed to provide a comprehensive assessment of the patient's shoulder condition, including pain, function, and range of motion. The ASES table is commonly used by orthopedic surgeons and physical therapists to evaluate and monitor patients with shoulder disease or those undergoing shoulder surgery [38].

Constant-Murley Shoulder Score, CMS

The Constant-Murley Shoulder Score (CMS) is a commonly used tool to evaluate patients' shoulder function. It was proposed by French surgeons Michel Constant and Maurice Murley in 1987 to evaluate the function and pain of the shoulder joint. The total score is pain score (15 points) + functional score (20 points) + mobility score (40 points) + strength score (25 points), with a maximum total score of 100 points [39].

The University of California at Los Angeles, UCLA

The University of California at Los Angeles (UCLA) Shoulder Rating Scale is a commonly used tool for assessing shoulder function and symptoms. This rating scale is designed to assess various aspects of shoulder health and is frequently used in clinical and research settings. Mainly include pain assessment, functional assessment, active and passive range of motion assessment, strength assessment, and patient satisfaction. Each component is scored individually, and the cumulative score provides an overall assessment of shoulder function. The UCLA Shoulder Joint Rating Scale is important for tracking changes in patients' shoulder conditions over time, monitoring treatment results, and guiding rehabilitation efforts [40].

The size and shape of calcification lesions

We will use ultrasonography to evaluate the size and shape of mixed calcification in the calcified area of RCCT.

The above indicators will be evaluated and analyzed in each group before treatment, 1 week, 2 weeks, 4 weeks after treatment, and 4 weeks of follow-up.

Participant timeline {13}

Participants will be assessed at baseline (T0), after 1 week (T1), 2 weeks (T2), 4 weeks (T3), and at 4 weeks of follow-up (T4). The participant timeline is outlined in the SPIRIT figure (Fig. 2).

Sample size {14}

According to the sample size calculation formula and combined with previous research, we estimated the effect size to be 0.5. The effect size $F=0.5$ was selected based on both clinical significance and prior research studies in similar contexts. The choice of effect size in clinical trials often balances between detecting a clinically meaningful difference and maintaining statistical power with a feasible sample size. Clinical assumption basis clinical significance: An effect size of 0.5 is generally considered to represent a moderate effect in clinical research. For the Visual Analog Scale (VAS) used to assess shoulder pain, a moderate effect would translate to a noticeable and clinically meaningful improvement in patients' pain levels post-treatment, which is both relevant and impactful in the context of treating rotator cuff calcific tendinitis (RCCT). Reference for effect size: A systematic review by Oudelaar et al. [41] on needle aspiration of calcific deposits for RCCT demonstrated effect sizes ranging from moderate to large in terms of pain reduction and functional improvement. This supports the selection of $F=0.5$ as a reasonable estimate for our study's effect size. Primary outcome using VAS Yes, the selected effect size of $F=0.5$ specifically pertains to the primary outcome, which is the patient's shoulder pain assessed using the Visual Analog Scale (VAS) after treatment. The VAS is a widely recognized and validated tool for measuring pain intensity, and an effect size of 0.5 represents a moderate but clinically significant improvement in pain levels, which aligns with our study objectives.

The sample size was calculated using G*power 3.1, the significance level was $\alpha=0.05$ (two-tailed), the estimated effect size was $F=0.5$, power $(1-\beta)=80\%$, and the number of groups = 3. We calculated the total sample size to be 48 people, and considering sample attrition, we planned to recruit 60 people.

Recruitment {15}

The study population will be recruited from the Department of Rehabilitation Medicine, Affiliated Hospital of Chengdu Sport University, Chengdu, China.

Assignment of interventions: allocation

Sequence generation {16a}

Random numbers generated by the SAS V.9.0 program.

Concealment mechanism {16b}

An independent, non-participating research assistant will place random numbers into opaque envelopes and open them in the assigned order.

Implementation {16c}

An independent research assistant will generate the allocation sequence and assign participants to interventions.

Assignment of interventions: blinding

Who will be blinded {17a}

Throughout the entire trial process, blinding will be employed for data collectors, statisticians, evaluators, and telephone follow-up personnel.

Procedure for unblinding if needed {17b}

Unblinding will be permissible only in cases of medical emergencies.

Data collection and management

Plans for assessment and collection of outcomes {18a}

Standardized assessment tools (VAS, ASES, CMS, UCLA) will be used. Two data managers who are not part of the study group and will be unaware of group assignments will be responsible for data entry and database establishment. All raw data related to the study will be stored at the Affiliated Hospital of Chengdu Sport University and uploaded to the clinical trial registry in real time.

Plans to promote participant retention and complete follow-up {18b}

To ensure participants remain engaged in the study and complete follow-up visits, the following detailed participant retention and follow-up plans have been developed:

1. Regular reminders and communication: Regularly remind participants of upcoming study visits and assessment times via phone calls, text messages, or emails. Send reminder messages 1 week and 1 day before each visit to ensure participants remember their appointments.
2. Personalized follow-up scheduling: Offer flexible visit times based on participants' schedules to facilitate their attendance. Provide home visits or remote video follow-up options for participants who have difficulty coming to the hospital.

Data management {19}

Data will be entered into Microsoft Excel and analyzed using SPSS 26.0. Double data entry and regular audits will ensure data quality.

Confidentiality {27}

Participant information will be stored securely and anonymized before analysis. All records will be securely stored for at least 10 years after the study to safeguard patient privacy.

Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

See above {26b} there will be no biological specimens collected.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

Repeated measures ANOVA will be used for primary and secondary outcomes. Bonferroni method for pairwise comparisons. Primary outcome: Pain level using the Visual Analog Scale (VAS).

Secondary outcomes: American Shoulder and Elbow Surgeons (ASES) score, Constant-Murley Shoulder Score (CMS), University of California at Los Angeles (UCLA) Shoulder Rating Scale, and size and shape of calcification lesions measured by ultrasonography.

Interim analyses {21b}

There will be no interim analysis in this study.

Methods for additional analyses (e.g., subgroup analyses) {20b}

Subgroup analyses will be performed based on demographic characteristics.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

When the lost-to-follow-up rates fall below 25%, an intention-to-treat analysis will be performed, and missing values will subsequently be imputed using the group mean via single imputation procedures.

Plans to give access to the full protocol, participant-level data, and statistical code {31c}

Relevant information may be provided upon request by the corresponding author.

Oversight and monitoring

Composition of the coordinating center and trial steering committee {5d}

At the start of the investigation, a steering committee will be established to oversee the trial. This committee will be led by the principal investigator (PI) and will consist of a small group to ensure efficient oversight of the trial's operations. The steering committee will meet weekly with the research team to discuss the study's progress and recommend countermeasures if deviations from the predetermined trial plan occur.

This regular interaction will ensure that any issues are promptly addressed and the trial remains on track.

Composition of the data monitoring committee, its role and reporting structure {21a}

In this research project, due to its small scale, controllable risks, and the absence of direct involvement in high-risk factors, there is no need to establish a data monitoring committee. Nonetheless, the project team ensures that all procedures comply with internal review, safeguard subject safety, and meet ethical and regulatory requirements.

Adverse event reporting and harms {22}

This study will monitor and report injection-related adverse events (AEs), such as needle-related infections, to the ethics committee during the treatment of RCCT. We will document the location, severity, treatment process, and recovery time of each AE and assess the causal relationship between the AE and the intervention. AEs will be used as safety outcome measures to evaluate the safety of the intervention.

Frequency and plans for auditing trial conduct {23}

The following measures will be put in place to ensure rigorous monitoring and auditing of trials:

(1) Project Management Group

Meeting frequency: The Project Management Group will meet bi-weekly to review trial conduct, assess progress, and address any operational issues. These meetings will focus on ensuring adherence to the trial protocol and addressing any deviations promptly.

(2) Trial Steering Group (TSG)

Meeting frequency: The TSG will meet quarterly throughout the trial period. These meetings will involve a thorough review of trial conduct, participant recruitment, and overall study progress. The TSG will provide strategic guidance and make decisions on any necessary protocol amendments or other significant issues.

(3) Independent Data Monitoring and Ethics Committee (IDMEC):

Meeting frequency: The IDMEC will convene semi-annually to review the conduct of the trial, monitor data quality, and ensure ethical standards are maintained. They will assess safety data, and interim results, and recommend whether the trial should continue as planned or if any modifications are necessary.

These regular meetings and reviews by the Project Management Group, TSG, and IDMEC will ensure continuous monitoring and effective oversight of the trial, maintaining the highest standards of scientific and ethical integrity.

Plans for communicating important protocol amendments to relevant parties (e.g., trial participants, ethical committees) {25}

In this study, any protocol amendments will be communicated to all relevant parties through the following official channels:

(1) Ethical committees: Protocol amendments will be submitted to the relevant ethical committees for review and approval. Notification will include detailed descriptions of the proposed changes and the rationale behind them. Approval from the ethical committees will be required before implementing any changes.
(2) Trial participants: Trial participants will be informed of significant protocol amendments through direct communication, which may include letters, emails, or in-person discussions during their next study visit. Participants will be provided with an updated consent form if the amendments affect their participation or the information they need to make an informed decision.
(3) Clinical trial registry: Approved protocol amendments will be promptly updated in the clinical trial registry to ensure transparency and public accessibility.
(4) Sponsor and funder: The study sponsor and funder will be notified of any protocol amendments through formal written communication, including detailed documentation of the changes and their impact on the study. This communication will ensure that the sponsor and funder are fully informed and can provide their input or approval as required.
(5) Trial steering committee (TSC) and data monitoring committee (DMC): Both the TSC and DMC will be informed of any protocol amendments during their regular meetings or through interim reports, ensuring continuous oversight and alignment with the trial's objectives.
(6) Documentation and reporting: Any deviations from the protocol will be fully documented using a breach report form. These reports will be reviewed by the Project Management Group and included in the trial master file.

Dissemination plans {31a}

Results will be published in peer-reviewed journals and presented at scientific conferences. In addition to publishing the results in peer-reviewed journals and presenting them at scientific conferences, we will also prepare a lay summary of the results for the patients involved in the study. This summary will be written in plain language to ensure that it is easily understandable by non-specialists. A clear and concise summary of the study results will be prepared. This summary will highlight the main findings, their significance, and any potential implications for patient care or future research. The lay summary will be distributed to all study participants through appropriate channels, such as mailed letters, emails, or during follow-up visits.

Discussion

The importance of treating RCCT

The significance and importance of treating RCCT is to improve the patient's quality of life, reduce pain, promote recovery, and avoid chronic progression. One of the main symptoms of RCCT is shoulder pain, especially during activity [41]. This can severely impact the patient's daily life, including work, household chores, and leisure activities. With effective treatment, pain can be reduced and the patient's quality of life improved. RCCT may cause injury and dysfunction of the rotator cuff tendons. Prompt treatment can help reduce inflammation, promote tissue repair, and improve shoulder joint function, allowing patients to move more freely. Untreated RCCT may lead to chronic inflammation and progression, ultimately affecting rotator cuff structure and function. Prompt treatment can help halt the progression of the disease, reduce the risk of chronic disease, and avoid complications. RCCT may cause complications such as rotator cuff tendon tears. With treatment, the risk of these complications can be reduced and the patient's recovery success rate improved.

Clinical significance and theoretical basis of ESW treatment

ESW therapy has important clinical significance in the treatment of RCCT. This treatment modality delivers high-energy sound waves to the damaged area, destroying calcification deposits and promoting local blood circulation. Theoretically, this could help reduce pain and improve joint function [42]. According to multiple studies, ESW can effectively reduce the size of calcifications within tendons, reduce pain scores, and improve shoulder joint range of motion [43, 44]. However, the therapeutic effect of ESW may be affected by factors such as the type of calcification, the energy level of the shock wave, and the frequency of application. Different studies have reported inconsistent efficacy, possibly due to differences in these variables. In addition, the mechanism of action of ESW is not limited to mechanical destruction of calcification, but may also involve biochemical reactions, such as promoting the release of inflammatory mediators, which all contribute to tissue self-repair and regeneration.

Clinical application and theoretical basis of PRP treatment

PRP therapy has attracted much attention in recent years in the treatment of tendon diseases. The growth factors and cytokines rich in PRP are thought to promote the healing and regeneration of damaged tendons. These growth factors, such as platelet-derived growth factor (PDGF) and transforming growth factor-β (TGF-β), play important roles in cell proliferation, differentiation, and collagen synthesis [45]. In the treatment of RCCT, the application of PRP aims to directly promote the repair of damaged areas by providing these growth factors [46]. Clinical studies have shown that PRP treatment can significantly reduce pain and improve joint function [47]. Nonetheless, the effects of PRP treatment vary among studies, which may be related to the PRP preparation method, injection technique, and patient-specific conditions.

Potential advantages of combined treatment with ESW and PRP

The combination of ESW and PRP in the treatment of RCCT can theoretically play a dual role. First, ESW reduces calcification deposition through physical means, providing a more favorable treatment environment for PRP. Secondly, the growth factors of PRP can directly act on damaged tendons to promote tissue repair and regeneration. The advantage of this combined treatment strategy is that it not only targets the symptoms of the disease (such as pain and functional limitations) but also targets the tissue damage during the pathological process. This comprehensive treatment approach may improve efficacy, shorten recovery time, and reduce the likelihood of recurrence. However, the final effect of this combined treatment approach needs to be verified through rigorous clinical trials.

In this study, we discuss the advantages of combination therapy, including its non-invasive, synergistic effects, and possible long-term effects. We also explore some possible limitations, such as individual differences, cost, and accessibility issues. By fully understanding this treatment option, we can better guide patients to choose the treatment that is best for their condition. We will discuss and analyze the results in detail from the following aspects. First, to interpret the results, we analyze the differences between the treatment group and the control group on major variables, including pain scores, shoulder

joint function, and calcification absorption. Explain possible reasons for these differences, such as the biological effects of ESW and PRP treatments. Second, compare with previous studies, compare our results with previous relevant studies, and discuss the consistency or differences. If there are conflicting results, explore possible reasons such as different study designs and sample characteristics. Third, efficacy and clinical significance, discussing the practical application and significance of the research results in clinical practice. If the treatment group performs better, the potential efficacy of ESW combined with PRP treatment in RCCT patients is emphasized. Fourth, limitations and future research directions: explore the limitations of our study, such as sample size and follow-up time. Possible directions for future research are proposed, such as larger-scale randomized controlled trials and long-term follow-up. Fifth, a discussion of methods and techniques discusses the advantages and limitations of the ESW and PRP treatments we employed in our study. Explore possible ways to improve or optimize treatment options. Sixth, implications for clinical practice explore how our research can provide new insights into the treatment of RCCT and guide clinical practice. Finally, a summary briefly summarizes the main findings of the study and reiterates the importance of the study and its clinical contribution.

Finally, through this study, we hope to open up a new way for the treatment of RCCT; provide patients with more effective, safe, and personalized treatment options; and also provide experience and inspiration for future research on similar diseases. In this era of continuous technological advancement, we are committed to bringing better medical services to patients and promoting the continuous development of medicine through scientific research.

Limitations

First, it is difficult to blind participants and intervention deliverers because they know what intervention is taking place. Second, short-term follow-up may not adequately assess long-term effects and potential complications. Long-term effects and safety are important aspects in assessing the effectiveness of a treatment. Finally, there is a certain degree of subjectivity in pain scores and other scores, which may have a certain impact on the results.

Trial status

Recruitment status: Not yet recruiting.

Trial registration date: April 17, 2024.

Date recruitment began: March 1, 2025.

Estimated primary completion date: July 2025.

Estimated study completion date: October 2025.

Abbreviations

RCCT	Rotator cuff calcific tendinitis
ESW	Extracorporeal shock wave
PRP	Platelet-rich plasma
VAS	Visual Analog Scale
ASES	American Shoulder and Elbow Surgeons
CMS	Constant-Murley Shoulder
UCLA	University of California at Los Angeles
PDGF	Platelet-derived growth factor
TGF-β	Transforming growth factor-β

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-024-08407-z.

Supplementary Material 1.

Acknowledgements

None.

Authors' contributions {31b}

WXF, XXL, and TZG conceived the trial protocol. All authors participated in collecting relevant information and data. WXF and XXL drafted and revised the manuscript, which all authors read and approved for submission.

Funding {4}

This study will be supported by the Medical Science Research Project of Hebei Province with grant number 20201405.

Availability of data and materials {29}

Data will be available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate {24}

This study will adhere to the Helsinki Declaration as revised in 2000 and to institutional and national regulations in China. This trial protocol was reviewed and approved by the Ethics Committee of Chengdu Sport University (2023–181). All participants will sign informed consent prior to inclusion in the study.

Consent for publication {32}

The participant information materials and informed consent form are available from the corresponding author on request.

Competing interests {28}

The authors declare that they have no competing interests.

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