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Efficacy of Tripterygium wilfordii granules in the treatment of plaque psoriasis: Protocol for a single-arm trial

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Study protocol

Keywords: Tripterygium wilfordii, plaque psoriasis, single-arm trial

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Abstract

Background

Tripterygium wilfordii is a traditional Chinese medicine renowned for its exceptional anti-inflammatory and immunomodulatory properties. Triptolide, the predominant compound found in *T. wilfordii*, has been extensively studied for its remarkable therapeutic effects in psoriasis treatment. However, the usage of triptolide is often hindered by uncontrollable adverse reactions, posing a considerable challenge. Consequently, it becomes imperative to effectively harness the benefits of triptolide while minimizing its drawbacks. In this study, we aimed to elucidate the molecular mechanism underlying the topical anti-inflammatory effects of triptolide, investigate the factors contributing to individual variations in response to triptolide, and identify potential markers for predicting the efficacy of triptolide in treating plaque psoriasis.

Methods

This was a single-arm study. All patients with plaque psoriasis who met the inclusion criteria were to be treated with Tripterygium granules for 4 weeks and followed up for 12 weeks. The improvement rate of the Psoriasis Area and Severity Index (PASI) score was the main therapeutic index. The relationship between C-terminal binding protein 1 (CtBP1) protein expression in skin lesions and the therapeutic effect was evaluated. We evaluated secondary indicators, including body surface area (BSA), Physician Global Assessment (PGA), Dermatology Life Quality Index (DLQI), Visual Analog Scale (VAS), traditional Chinese medicine (TCM) syndrome score, relapse rate, and body surface area. Safety indicators included vital signs, routine blood tests, liver function, renal function, physical examination, adverse events and serious adverse events.

Discussion

T. wilfordii granules are a frequently prescribed Chinese medicine for psoriasis treatment. However, the effectiveness of this medicine varies among patients, with some experiencing poor results. The level of serum CtBP1 expression differs between patients who respond positively to *T. wilfordii* granules and those who do not. Therefore, CtBP1 has the potential to serve as a crucial indicator in predicting the efficacy of *T. wilfordii* granule treatment of plaque psoriasis.

Trial registration ChiCTR.govChiCTR2000036398. Registered on August 22, 2020.

Administrative information

Title {1}	Efficacy of *Tripterygium wilfordii* granules in treatment of plaque psoriasis: Protocol for a single-arm trial
Trial registration {2a and 2b}	ChiCTR.gov registration number: ChiCTR2000036398; registration date: August 22, 2020; registration title: Precise clinical research on the topical treatment of plaque psoriasis with triptolide
Protocol version {3}	Version 2.0 from 10/02/2021
Funding {4}	The study was funded by the Clinical Research Plan of Shanghai Shenkang Hospital Development Center (No. SHDC2020CR4041), National Natural Science Foundation of China (No. 82004366, 82074428), Shanghai Municipal Commission of Science and Technology (No. 20XD1423600), Innovative Team Projects of Shanghai Municipal Commission of Health (No. 2022CX011), Young Qi-Huang Scholar of National Administration of Traditional Chinese Medicine, Sailing Program of Shanghai Rising-Star Program (No. 22YF1449700), Evidence-Based Capacity Building for TCM Specialty Therapies for Skin Diseases of National Administration of TCM, Shanghai University of Traditional Chinese Medicine Industrial Development Center (No. YYKC-2021-01-023, YYKC-2021-01-156).
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Name and contact information for the trial sponsor {5b}	Fu-lun Li, Email: drlifulun@163.com
Role of sponsor {5c}	Fu-lun Li initiated the clinical study and designed the entire research protocol.

Background

Plaque psoriasis is a chronic inflammatory skin disease characterized by frequent recurrence and mediated by autoimmune processes, posing considerable challenges to patients' physical and mental well-being[1] as well as their overall quality of life. Over the past few years, there has been a noticeable increase in the prevalence of psoriasis, with rates in China rising from 0.12% in 1984 to 0.47% in recent times[2]. Many patients with mild to moderate plaque psoriasis have concerns about the potential side effects associated with long-term systemic use of hormones and immunosuppressants[3]. Additionally, the high cost of biological agents further compounds their worries. Consequently, there is an escalating demand for effective and affordable topical medications, as well as traditional Chinese medicine treatments, among such patients[4].

T. wilfordii, also known as "Huangteng root" and "Broken Intestinal Herb," was first documented in the Addendum of Compendium of Materia Medica written by Zhao Xuemin in 1765[5]. It possesses various medicinal properties, including dispelling wind and dredging collaterals, relaxing muscles and promoting blood circulation as well as relieving pain and reducing swelling[5]. Due to its potent anti-inflammatory and immunosuppressive effects, *T. wilfordii* is extensively utilized in traditional Chinese medicine for treating autoimmune diseases such as psoriasis, rheumatoid arthritis, and kidney diseases[3, 6]. However, the clinical usage of *T. wilfordii* preparations is limited by potential toxicities to the liver, kidney, blood system, and reproductive system[7]. Addressing this urgent issue of minimizing side effects while ensuring therapeutic efficacy requires further exploration in clinical and basic research.

Triptolide, a compound derived from *T. wilfordii*, exhibits notable pharmacological effects, such as antirheumatic, antibacterial, anti-inflammatory, immunomodulatory, and antitumor properties[8]. Researchers have recently taken a keen interest in its substantial clinical potential. Triptolide has the capacity to suppress proliferation and induce apoptosis in various cancer cells, including aggressive prostate and pancreatic cancer[9]. Moreover, inhibiting the NF-κB/TNF-α/vascular cell adhesion molecule-1 signaling pathway can alleviate the inflammatory response associated with rheumatoid arthritis[10]. *T. wilfordii* was investigated for its efficacy in autoimmune dermatosis, particularly psoriasis, as early as 1985. Xu *et al.* [11] demonstrated the therapeutic benefits of *T. wilfordii* in psoriatic arthritis and pustular psoriasis. Similarly, Han *et al.* [12] observed that *T. wilfordii* can effectively treat psoriasis by reducing the levels of inflammatory factors such as IL-12, IL-23, and TNF-α. Undoubtedly, *T. wilfordii* holds considerable promise and potential in the treatment of autoimmune diseases. However, its clinical utility is often hampered by uncontrollable adverse reactions[7]. While some patients experience substantial improvements, others may encounter severe adverse effects. The underlying reasons for these inconsistencies remain unclear. Consequently, finding ways to leverage the advantages of triptolide while mitigating its limitations presents a considerable challenge that necessitates immediate attention.

Here, we conducted a single-arm trial to investigate the underlying factors behind individual variations in response to *T. wilfordii* as well as to identify potential markers for predicting the effectiveness of *T. wilfordii* in the topical treatment of plaque psoriasis.

Study Objectives

The main efficacy index used to assess the relationship between the clinical efficacy of *T. wilfordii* granules and C-terminal binding protein 1 (CtBP1) expression levels was the improvement rate of the Psoriasis Area and Severity Index (PASI) score after a 4-week treatment. This evaluation was designed to determine whether the findings were consistent with previous basic studies. Thus, the objective was to clarify the impact of CtBP1 expression levels in keratinocytes of psoriatic lesions on the therapeutic effect of triptolide.

Methods

Study setting

This clinical trial was a single-arm study. The study subjects were all patients with plaque psoriasis from Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of Traditional Chinese Medicine. The technical roadmap in research process 1 is shown in Fig. 1.

The clinical trial was approved by the Institutional Review Board (IRB) of Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of TCM (ethical approval number: 2020–087), and the study is registered at http://www.chictr.org.cn/(ID: ChiCTR2000036398; registration date: August 22, 2020). We have written this article in full compliance with the SPIRIT reporting guidelines [13]. The SPIRIT checklist is shown in Additional file 1.

Diagnostic Criteria

The participants were patients with plaque psoriasis. In Western medicine, the diagnostic criteria for plaque psoriasis have been formulated in accordance with *the Guidelines for the Diagnosis and Treatment of Psoriasis in China (2018 simplified edition)*[14]. The dialectical diagnostic criteria of traditional Chinese medicine have been drafted according to the *Evidence-based clinical practice guide for psoriasis vulgaris* by the Dermatology Branch of China Association of Chinese Medicine [15].

Participants were required to meet the following diagnostic criteria[14]: initially, the lesions appear as large inflammatory red papules ranging in size from needle tips to lentils, often distributed in a guttate pattern. These papules rapidly enlarge and become covered with silvery multilayered scales resembling mica. Additionally, upon scale peeling, the film phenomenon and cribriform hemorrhage can be observed. The base of the lesions is infiltrated, and an isomorphic reaction may occur. Furthermore, older rashes may exhibit nummular, discoid, or geographic characteristics. Histopathological examination reveals epidermal hyperkeratosis and hypokeratosis. Neutrophilic polymorphonuclear leukocytes accumulate in the stratum corneum, while the spinous layer thickens. Moreover, there is regular extension of epidermal processes downward, rod-like dermal papilledema, dilation of intrapapillary vessels, and the presence of perivascular inflammatory cell infiltrates.

Inclusion and exclusion criteria

The recruitment of participants for this trial was conducted exclusively at Yueyang Hospital of Integrated Traditional Chinese and Western Medicine. Participants were informed about the study through recruitment advertisements. Before the study began, one or two designated research observers comprehensively explained the trial to potential participants. Subsequently, participants were provided with an informed consent form to voluntarily sign. The consent form included guidance and provisions for participants to indicate their agreement to the use of their data if they withdraw from the trial. Importantly, this trial involved collection of skin biological samples from the subjects. This information was clearly stated in the informed consent form, and the participant was fully informed. Naturally, this process was carried out with the subject's permission and cooperation.

The inclusion requirements consisted of the following conditions: (1) meet the diagnostic criteria for plaque psoriasis; (2) age ranging from 18 to 60 years, inclusive of both 18 and 60 years; (3) course of disease ranging from 0 to 30 years; (4) lesion area less than 3% of the total body surface area (BSA); (5) patients must sign the informed consent form, and upon discussion with the ethics committee, volunteer to receive treatment, undergo observation, and undergo various examinations; (6) no history of diseases related to the heart, liver, kidneys, digestive system, nervous system, mental health or metabolic disorders.

Exclusion criteria included the following: (1) pregnant and lactating women or women who became pregnant during the study period; (2) systemic therapy was used within 3 months, including extensive topical potent corticosteroids and immunosuppressive agents; (3) patients with concomitant primary diseases such as cardiovascular, cerebrovascular, liver, kidney, hematopoietic system, and mental illness; (4) patients with plaque psoriasis on the head and face; and (5) allergy to *T. wilfordii* granules.

Withdrawal criteria and termination criteria

During this study, subjects had the right to withdraw from the study at any time. If the subject requested to withdraw from the study, the investigator truthfully recorded the reasons for withdrawal in detail. If the subject was determined to terminate the experiment, all relevant original data were saved for data analysis and original data verification after the end of the experiment.

Subjects who met the specified termination criteria were deemed to have concluded their participation in the study. These criteria included (1) reaching the end of the observation window, (2) expressing unwillingness to continue being observed, and (3) experiencing a recurrence of skin lesions that met the defined criteria for recurrence and necessitated additional drug treatment.

In the final stage of data analysis, subjects who met the following exclusion criteria were excluded from the trial results analysis: (1) subjects whose disease worsened (PASI $\geq$ 125% of baseline PASI) and were determined by the study physician to require new treatments such as extra-strong topical glucocorticoids, systemic glucocorticoid therapy, or traditional Chinese medicine preparations; (2) subjects who did not adhere to drug usage regulations, causing an inability to assess efficacy, or had incomplete data that could impact efficacy or safety evaluation; (3) subjects who were lost to follow-up and voluntarily withdrew from the study; (4) subjects who used drug therapies listed in the exclusion criteria during the study, including strong topical glucocorticoids, systemic glucocorticoid therapy, and traditional Chinese medicine preparations; (5) subjects who developed new diseases, including skin conditions, that directly affected the assessment of clinical status throughout the study period; (6) subjects with severe disease occurring throughout the study period; and (7) subjects who became pregnant during the study or exhibited endurance toward the study or experienced serious adverse reactions.

Randomization and masking

Not applicable.

Interventions

This clinical study was a single-arm study. All patients were recruited and treated with wet compresses of *T. wilfordii* granules (China Resources Sanjiu Traditional Chinese Medicine Formula Granules). The specific procedure involved dissolving 10 g of China Resources Sanjiu *T. wilfordii* granules in 50 ml of distilled water and ensuring even mixing. Then, sterile gauze (4 layers) was soaked in the liquid medicine and applied externally to the skin lesions for 20 minutes twice a day. After four weeks of continuous treatment, the improvement rate of the PASI score was used as the primary efficacy measure for assessment. Additionally, prior to treatment, subjects underwent an evaluation of CtBP1 protein expression at the affected skin areas.

Study visit overview

Subjects were scheduled for follow-up visits at weeks 0, 1, 2, 3, 4, 12, and 16 of the trial, with laboratory tests conducted at weeks 0 and 4. The interval between each follow-up visit was two days. In cases where subjects were unable to attend the follow-up visits on time, researchers maintained contact through phone calls or messages. Subjects were reminded to come to the hospital for their scheduled follow-up visits or asked about their experiences and treatment effects. During each follow-up visit, the investigator promptly recorded the relevant trial data of the subjects in the case report form (CRF). At the start of the trial, participants received the necessary intervention medication. During each follow-up visit, any remaining drugs were collected, and new drugs were provided. The details of these transactions were documented in the release/recall drug record form. Participants' adherence to the treatment was assessed based on feedback received, while details of any adverse events were accurately recorded. The research flow chart is presented in Table 1. For subjects who complete the trial, they will receive a transportation allowance of RMB 100 at the end of the trial.

Table 1
Study flow chart

Test phase	Screen 1	Baseline Period	Drug treatment period				Follow-up Period	
Visits	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Visit (weeks)	**/**	**0**	**1**	**2**	**3**	**4**	**12**	**16**
Visit (days)	**− 7 to -1**	**0**	**7 ± 3**	**14 ± 3**	**21 ± 3**	**28 ± 3**	**84 ± 5**	**112 ± 5**
General conditions								
Informed Consent Form	X							
Demographic data		X						
Psoriasis history and treatment history		X						
Other medical and treatment history		X						
Randomized								
Inclusion and exclusion criteria check	X							
Efficacy evaluation								
PASI		X	X	X	X	X	X	X
BSA		X	X	X	X	X	X	X
PGA		X	X	X	X	X	X	X
DLQI		X	X	X	X	X	X	X
PRQoL		X						
VAS		X	X	X	X	X	X	X
TCM score		X						
Lesional photography		X				X	X	X
Safety Evaluation 2								
Vital Signs		X				X		
Adverse events		X	X	X	X	X	X	X
Serious adverse event		X	X	X	X	X	X	X
Other Transactions								
TCM body mass scale		X						
Personal life cycle		X				X		
Medical expenses		X	X	X	X	X		
Patient satisfaction		X				X		
Dispense medication		X	X	X	X			
Concomitant medication		X	X	X	X	X	X	X
Data during the screening period should be recorded in the baseline period.								

Outcomes

Main indicators

The primary outcome measure utilized in this study was the PASI as presented in Table 2. The assessment of patients' skin lesions was conducted prior to treatment initiation, at weeks 1, 2, 3, and 4 during the treatment phase, and during the follow-up period at weeks 12 and 16. The calculation formula of the efficacy evaluation criteria (nimodipine method) was [(pretreatment score - posttreatment score)/pretreatment score] × 100%. The calculated values were assessed using Table 1 as the evaluation criteria. The efficacy was determined based on the categories of recovered, significantly effective, effective, or ineffective (Table 3).

Table 2
Psoriasis area and severity index (PASI)

Area and fraction (A)		0	1	2	3	4	5	6	Systemic Score				Local intervention lesion scores
									Head and neck	Upper limb	Trunk	Leg	
		0%	1–9%	10–29%	30–49%	50–69%	70–89%	90–100%					
Clinical symptoms	Score	**0 (none)**		**1 (mild)**		**2 (Moderate)**	**3 (Severe)**	**4 (very severe)**	**Head and neck**	**Upper limb**	**Trunk**	**Leg**	
	Erythema (E)	No erythema visible		Slight erythema		Obvious erythema	Bright red or dark red	Deep red or dark red					
	Infiltration (I)	Lesions flush with normal skin		Lesions slightly elevated above normal skin surface		Moderate elevation with rounded or sloping edge of plaque	Lesions are highly thickened and extremely elevated	Lesions are highly thickened and extremely elevated					
	Desquamation (D)	No visible scaling on the surface		Some lesions are covered with scales on the surface, mainly subtle scales		Most lesions are completely or incompletely covered with scales on the surface, which was patchy	All lesions were covered with scales on the surface, which was thick and layered	All lesions were covered with scales on the surface, which were very thick and layered					

Note: Half score can be used in symptom score, but only 1.5 and 2.5 points can be used, and 0.5 and 4.5 points cannot be used; if the patient still has any symptoms, at least 1 point can be used (according to PASI guidelines).

PASI = head area score × (E + I + D) × 0.1 + upper limb area score × (E + I + D) × 0.2 + trunk area score × (E + I + D) × 0.3 + lower limb area score × (E + I + D) × 0.4; local intervention lesion score = E + I + D

Table 3
Psoriasis efficacy evaluation indicators

Clinical recovery	☐ 1	**All lesions regressed, or only a few inconspicuous small lesions had a decrease in PASI score of more than 95%, loss of itching, and an efficacy index ≥ 95%**
Markedly effective	☐ 2	The PASI score of the lesion decreased by 70–94%, and the itching was significantly reduced, 70% ≤ efficacy index < 95%
Effective	☐ 3	The PASI score of skin lesions decreased by 30–69%, the itching was alleviated, and 30% ≤ efficacy index < 70%
Invalid	☐ 4	The PASI score of the lesion decreased by less than 30%, the itching was not reduced, and the efficacy index was < 30%

Secondary indicators

The study's secondary endpoints encompassed various factors, including the BSA of skin lesions, Physician Global Assessment (PGA), Dermatology Life Quality Index (DLQI), visual analog scale (VAS), traditional Chinese medicine (TCM) syndrome score, relapse rate, and body surface area. Throughout the study, assessments were conducted for BSA, PGA, DLQI, and VAS. However, evaluations for TCM symptom score and body surface area took place prior to treatment only. Furthermore, personal life history and patient satisfaction were examined both before treatment and after a 4-week treatment period. Recurrence determination and evaluation were performed during the follow-up phase. If new lesions appeared, a baseline PASI with a lesion score higher than 50% at the visit was defined as lesion recurrence. Similarly, if the lesion worsened compared to the original condition, a baseline PASI with a lesion score higher than 125% at the visit was classified as worsening. Following the completion of the 4-week investigational treatment cycle, patients who have recovered underwent off-treatment observation until week 16. However, if the patient's rash remained unhealed or progressed, the investigator provided routine clinical medical services and follow-up for 16 weeks, culminating in the completion of the Concomitant Medication Form.

Safety indicators

Evaluation of safety indicators included monitoring vital signs, routine blood tests, liver function, renal function, physical examination, adverse events and serious adverse events. Assessments for vital signs, routine blood tests, liver function, and renal function were conducted prior to treatment initiation and after a 4-week duration. Additionally, continuous monitoring and recording of adverse events and serious adverse events were carried out throughout the study. In the event of adverse events occurring during the research trials, immediate action was taken to provide active treatment. Moreover, if any serious adverse events occurred, the trial was promptly discontinued, and the patient was immediately referred to a specialist.

Sample size

Based on previous literature research[12], it is expected that in this study, the effective rate of topical triptolide in the treatment of plaque psoriasis is P = 75%; assuming the allowable error δ = 0.1P, the design efficiency DF is taken as 1.5 (based on the withdrawal rate of treatment being approximately 20%), α = 0.05, Uα = 1.96; according to the sample size calculation formula:

$$N = DF \times \frac{U_{\alpha}^{2} \times P(1 - P)}{\delta^{2}}$$

The estimated sample size is 192. A total of 192 subjects diagnosed with plaque psoriasis were to be included in this study.

Data collection, management, and quality control

The research data obtained during the research process was diligently recorded in the case report form (CRF) by the responsible researcher. Furthermore, the researcher endorsed the CRF with their name and documented the date of collection. To ensure efficient data management, we utilized the Clinical Research Information Platform (CRIP). Each data entry was thoroughly scrutinized by two data managers before being finally entered into the CRIP system. We guaranteed strict confidentiality for all information, including personal details of the subjects, CRFs, laboratory tests, and other relevant data. The CRIP system did not display subject names but instead utilized subject numbers for identification purposes. And in the middle of this project, the trial procedures would be monitored by the clinical research unit (CRU).

Statistical analysis

Descriptive statistical analysis involves describing qualitative indicators using frequency, percentage, or constituent ratio. Quantitative indicators are expressed as the mean and standard deviation if they follow a normal distribution and as the median and interquartile range if they do not adhere to a normal distribution.

Comparative analysis of qualitative data was performed using the Chi-square test, Fisher's exact probability test, Wilcoxon rank sum test, and CMH 2 test. Quantitative data were in accordance with the normal distribution with the t test (homogeneity test of variance was performed, 0.05 was used as the test level, and the Satterville method was used for the corrected t test when the variances were unequal), and the Wilcoxon signed rank sum test was used for the Wilcoxon test for normal distribution without the normal distribution. The hypothesis test was uniformly used to give the test statistics and their corresponding P values, and P < 0.05 was considered statistically significant. Correlations of ordinal categorical variables were analyzed using Spearman's rank correlation or Kendall's pottery correlation coefficient.

Discussion

Psoriasis is an inflammatory disease, and the precise mechanism underlying its pathogenesis remains incompletely understood. One important factor contributing to psoriasis pathogenesis and progression is the dysregulated transcriptional regulation of inflammatory cytokines caused by the hyperactivation of NF-κB through transcription factors (TFs) [16]. Gene transcription regulation is a complex biological process that involves a diverse array of regulatory proteins associated with transcription. Currently, apart from NF-κB, there exists a limited understanding of other proteins implicated in the transcriptional regulation of psoriasis and its related mechanisms. This lack of knowledge poses a certain impediment to comprehending psoriasis and impairs the development of therapeutic drugs targeting the condition.

CtBP1 represents a widely distributed class of transcriptional corepressors in animal cells[17]. While its primary function has traditionally been recognized as transcriptional repression of downstream genes, recent studies have revealed that CtBP1 can also act as a transcriptional activator under specific conditions[18]. Additionally, CtBP1 plays a crucial role in responding to changes in intracellular redox status, with its activity primarily influenced by the NADH/NAD + ratio within the cell[19]. Disruptions in cellular and systemic glucose metabolism or exposure to hypoxia can alter the NADH/NAD + ratio[20]. Under hypoxic conditions, the intracellular NADH/NAD + ratio increases, thereby enhancing CtBP1 activity and subsequently increasing the level of transcriptional repression of downstream genes[19]. In recent years, two studies published in Nature Communications and Cell have contributed to notable advancements in our understanding of CtBP1's role in inflammation development. These studies have revealed that CtBP1 acts as a crucial transcriptional regulator. Specifically, it has been found that CtBP1 can bind to the transcription factor ERβ and the P300 transcriptional coactivator. Through these interactions, CtBP1 effectively inhibits the transcription of downstream inflammatory cytokines such as IL-23, IL-1β, and TGF-β, among others[20, 21]. This inhibition ultimately leads to the suppression of the inflammatory response. Furthermore, Hong *et al.*[22] conducted research showing that mice overexpressing CtBP1 in epidermal keratinocytes exhibited severe skin inflammation. However, the use of CtBP inhibitors successfully reduced the expression of CtBP-regulated proinflammatory genes, resulting in a significant reduction in psoriatic lesions in mice.

The results of our previous basic research experiments have indicated a correlation between the expression level of CtBP1 in keratinocytes and the extent of inhibition of inflammatory cytokine expression by triptolide, which influences the effectiveness of topical treatment. In cases where intracellular CtBP1 expression was absent, triptolide exhibited “off-target effects.” Consequently, it failed to inhibit inflammatory cytokines downstream of CtBP1 and even promoted the expression of certain inflammatory cytokines, rendering topical treatment ineffective. Based on our prior research and a comprehensive analysis of relevant clinical studies, we propose that CtBP1 functions by transcriptionally inhibiting a range of psoriasis-related inflammatory cytokines. Furthermore, the absence of CtBP1 expression emerges as a significant factor contributing to the pathogenesis and progression of psoriasis. Notably, CtBP1 may serve as a pivotal molecule directly impacting the anti-inflammatory effects of triptolide.

The objective of this clinical study was to investigate whether the correlation between the variation in external response to triptolide and the intensity of CtBP1 expression in subjects with plaque psoriasis aligned with previous findings from basic research. This study offered novel insights for the development of personalized treatment strategies using TCM active substances. Additionally, it served as a valuable resource for scholars by enhancing our understanding and refining the application of TCM in clinical psoriasis treatment. The outcomes of this clinical study will also contribute greatly to elucidating the new anti-inflammatory regulatory mechanism of CtBP1 in triptolide-based treatment of plaque psoriasis.

Trial status

Recruitment commenced in March 2021, and the study would conclude in 2023. The majority of patients had been recruited as of the submission. They were currently being treated or followed up.

The protocol received approval from the ethics committee, and financial support was obtained in 2020. Additionally, an electronic case report form (eCRF) was developed. Patient enrollment was scheduled to take place from 2021 to 2023. Currently, we are engaged in patient recruitment and data analysis.

Abbreviations

PASI Psoriasis Area and Severity Index

CtBP1 C-terminal binding protein 1

BSA Body Surface Area

PGA Physician Global Assessment

DLQI Dermatology Life Quality Index

VAS Visual Analog Scale

TCM Traditional Chinese Medicine

CRF Case Report Form

IRB Institutional Review Board

CRIP Clinical Research Information Platform

CRU Clinical Research Unit

TFs Transcription Factors

eCRF Electronic Case Report Form

Declarations

Supplementary information

Additional file 1. SPIRIT Checklist

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Authors' contributions

FLL, JYZ, WJG, and DJG participated in the study design; FLL, JYZ and YJD directed the study design; LYC and DJG wrote the manuscript; WJG, XL, and YW were responsible for passing the ethical review; PYW, RFX and GY prepared additional documents; and DJG, HZL and TD revised the manuscript. All authors have read and agreed to the final draft.

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Availability of data and materials

The datasets analyzed during the current study and the statistical code as well as the full protocol are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

Ethics approval was obtained from the institutional review board of Yueyang Hospital of Integrated Traditional Chinese and Western Medicine (ethical approval number: 2020–087). The trial was registered on August 22, 2020, on ChiCTR. gov website with trial identification number ChiCTR2000036398. Written informed consent will be obtained from all individual participants included in the study.

Consent for publication

Participants in the study signed an informed consent form, which includes consent for publication.

Competing interests

All authors and investigators declare that they have no competing interests.

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Figures

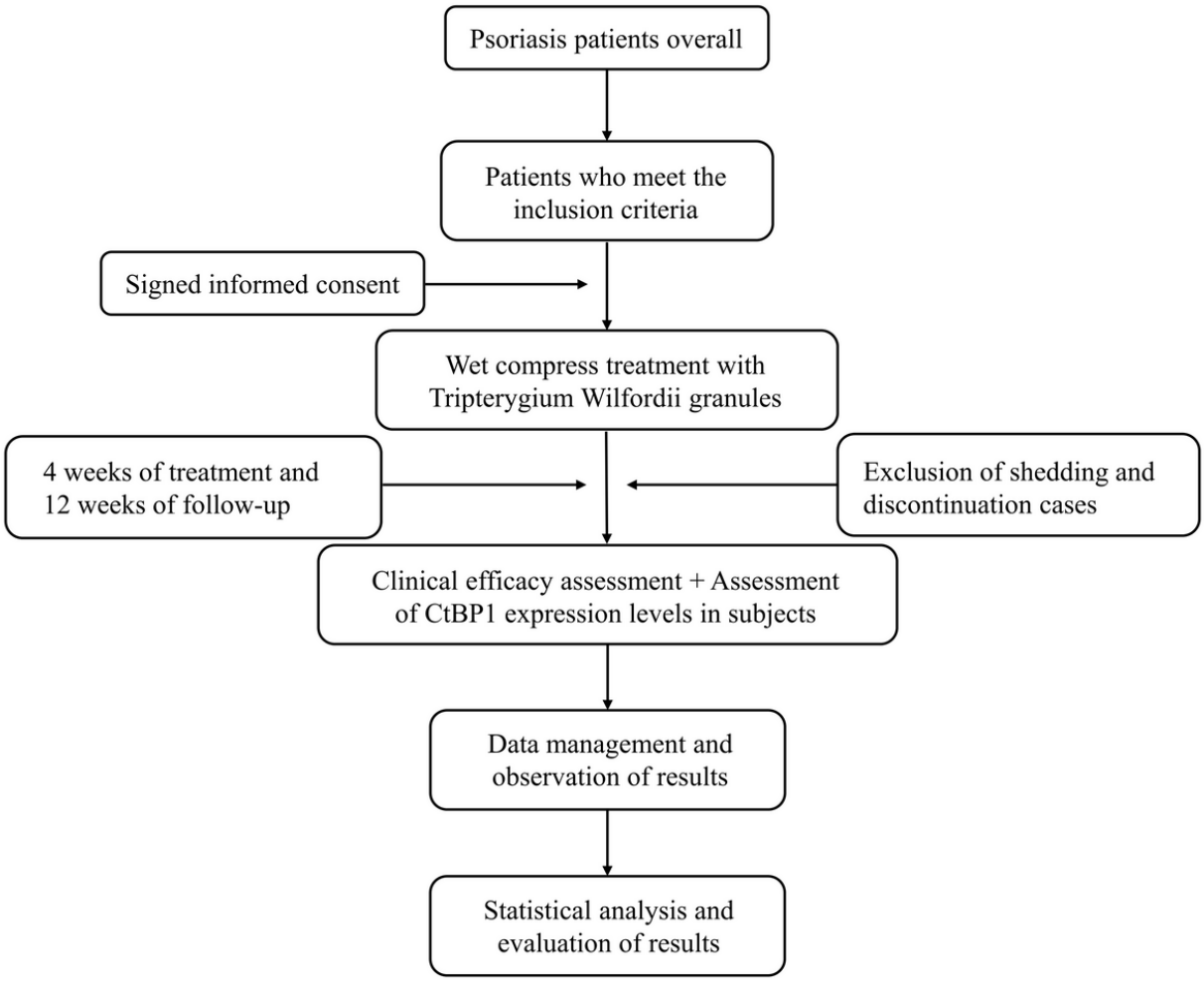


Figure 1

Technology roadmap

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