ISRCTN91905052 https://doi.org/10.1186/ISRCTN91905052

Can Chinese herbal medicine help prevent relapse after ixekizumab treatment in adults with moderate-to-severe plaque psoriasis?

Submission date
01/05/2026

Recruitment status
Recruiting

Registration date
01/05/2026

Overall study status
Ongoing

Last Edited
01/05/2026

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Plaque psoriasis is a long-term inflammatory skin disease that can cause red, scaly and itchy skin lesions and has a high risk of relapse. Biologic treatment with ixekizumab can work well, but relapse after stopping or stepping down treatment remains a major problem. Chinese herbal medicine has been widely used in China to help control relapse and improve quality of life, but more high-quality clinical evidence is needed. This study aims to find out whether Chinese herbal medicine given after successful ixekizumab treatment can reduce relapse in adults with moderate-to-severe plaque psoriasis.

Who can participate?
Adults aged 18 to 70 years with moderate-to-severe plaque psoriasis who meet the study eligibility criteria.

What does the study involve?
The study has two stages. In the first stage, eligible participants receive ixekizumab induction treatment for 12 weeks. Participants whose psoriasis improves sufficiently after this first stage will enter the second stage. In the second stage, they will be randomly assigned to receive either active Chinese herbal medicine or a matched placebo for 12 weeks. During this stage, neither the participants nor the study team assessing outcomes will know whether active or placebo Chinese herbal medicine has been assigned. After treatment, participants will be followed for 36 weeks. The study will assess relapse, psoriasis severity, itch, quality of life and safety.

What are the possible benefits and risks of participating?
Participants may or may not benefit directly. The study may help identify a better way to prevent psoriasis relapse after biologic treatment. Risks include side effects from ixekizumab, possible side effects from Chinese herbal medicine, allergic reactions, infection, worsening of psoriasis, and inconvenience from repeated visits and assessments.

Where is the study run from?
This is a multicentre study in China led by Guangdong Provincial Hospital of Chinese Medicine.

When is the study starting and how long is it expected to run for?
The first participant entered the study on 23 December 2024. Recruitment is expected to continue until 7 November 2027. The study is expected to finish on 31 December 2028.

Who is funding the study?
Guangdong Provincial Hospital of Chinese Medicine provides institutional and material support. External grant funding is currently under application.

Who is the main contact?
Dr Jingjie Yu
Guangdong Provincial Hospital of Chinese Medicine
jingjieyu@gzcum.edu.cn

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Dr Jingjie Yu

Contact details
No. 111 Dade Road, Yuexiu District
Guangzhou
China
510120
+86-20-81887233-35934
jingjieyu@gzcum.edu.cn

Additional identifiers

Study information

Scientific Title
A multicentre sequential randomized, blinded, placebo-controlled study in adults with moderate-to-severe plaque psoriasis to evaluate whether Chinese herbal medicine, after PASI-75 response to 12-week ixekizumab induction, reduces relapse compared with matched placebo

Study objectives
1. To determine whether sequential Chinese herbal medicine treatment after successful ixekizumab induction reduces psoriasis relapse in adults with moderate-to-severe plaque psoriasis
2. To compare time to relapse, PASI improvement, PASI75 response, PASI90 response, PGA score, pruritus VAS score, BSA score, DLQI score, Skindex-16 score, and adverse reaction rate between the active-treatment group and the placebo group

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 27/06/2025, Ethics Committee of Guangdong Provincial Hospital of Chinese Medicine (Guangdong Provincial Hospital of Chinese Medicine, No. 111 Dade Road, Yuexiu District, Guangzhou, 510120, China; +86-20-81887233-35943; llbgs@gzucm.edu.cn), ref: BF2024-136-02

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Sequential

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Moderate-to-severe plaque psoriasis

Interventions
This is a multicentre sequential interventional study with two stages.

Stage 1 (induction stage): up to 200 eligible adults with moderate-to-severe plaque psoriasis will receive ixekizumab induction treatment for 12 weeks. Ixekizumab will be administered subcutaneously at 160 mg at Week 0, followed by 80 mg every 2 weeks until Week 12.

Stage 2 (randomized stage): participants who achieve PASI75 after ixekizumab induction will be randomized centrally in a 1:1 ratio using a SAS-generated randomization schedule and a web-based central randomization system to one of two groups.

Group 1: active Chinese herbal medicine. Participants will receive Guben Qushi Huayu Granules, 3 sachets orally twice daily, plus Shenling Baizhu Powder Capsules, 3 capsules orally three times daily, for 12 weeks.

Group 2: matched placebo. Participants will receive placebo Guben Qushi Huayu Granules, 3 sachets orally twice daily, plus placebo Shenling Baizhu Powder Capsules, 3 capsules orally three times daily, for 12 weeks.

Only the Chinese herbal medicine allocation will be blinded. Matching placebo preparations will be used so that participants, treating clinicians, and outcome assessors are unaware of whether active or placebo Chinese herbal treatment has been assigned. During the 12-week randomized treatment period, visits will occur every 2 weeks. After treatment, all randomized participants will be followed for 36 weeks with visits every 4 weeks.

A 10% urea ointment may be used as background topical treatment during treatment and follow-up.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ixekizumab, Guben Qushi Huayu Granules, Shenling Baizhu Powder Capsules, Placebo Guben Qushi Huayu Granules, Placebo Shenling Baizhu Powder Capsules, 10% urea ointment

Primary outcome(s)
1. Psoriasis relapse rate among participants who achieved PASI75 at the end of ixekizumab induction measured using Proportion of randomised participants meeting the protocol-defined relapse criterion, assessed using investigator-assessed Psoriasis Area and Severity Index (PASI) at Every 2 weeks during the 12week randomised treatment period, every 4 weeks during the 36week followup period after randomisation, and at any unscheduled worsening visit

Key secondary outcome(s))
1. Time to psoriasis relapse measured using Time interval from randomisation baseline to first protocol-defined relapse, assessed using investigator-assessed Psoriasis Area and Severity Index (PASI) at Continuously assessed from randomisation baseline to end of follow-up, with formal assessments every 2 weeks during the 12-week randomised treatment period and every 4 weeks during the 36-week follow-up period

2. Improvement in psoriasis severity measured using Percentage improvement in Psoriasis Area and Severity Index (PASI) calculated using investigator-assessed PASI at Randomisation baseline and every scheduled study visit, every 2 weeks during the 12-week randomised treatment period and every 4 weeks during the 36-week follow-up period

3. PASI75 response rate measured using Proportion of participants achieving at least 75% improvement from randomisation baseline in investigator-assessed Psoriasis Area and Severity Index (PASI) at Randomisation baseline and every scheduled study visit, every 2 weeks during the 12-week randomised treatment period and every 4 weeks during the 36-week follow-up period

4. PASI90 response rate measured using Proportion of participants achieving at least 90% improvement from randomisation baseline in investigator-assessed Psoriasis Area and Severity Index (PASI) at Randomisation baseline and every scheduled study visit, every 2 weeks during the 12-week randomised treatment period and every 4 weeks during the 36-week follow-up period

5. Dermatology-specific quality of life measured using Dermatology Life Quality Index (DLQI) at Before biologic induction, after biologic induction and before randomised intervention, at the end of the randomised treatment period, and at relapse or end of follow-up

6. Treatment-related adverse reaction rate measured using Proportion of participants with investigator-assessed and recorded treatment-related adverse events using adverse event reporting data at Continuously throughout the study, including the 12-week randomised

treatment period and the 36-week follow-up period, recorded at each scheduled visit and any unscheduled safety visit

Completion date
31/12/2028

Eligibility

Key inclusion criteria
1. Adults aged 18 to 70 years
2. Diagnosis of moderate-to-severe plaque psoriasis
3. PASI score ≥7 or body surface area involvement≥10%
4. Meets the indication criteria for ixekizumab treatment
5. Willing and able to provide written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Pregnant or lactating women, or participants planning pregnancy during the study period
2. Inflammatory bowel disease
3. Serious uncontrolled primary disease of the respiratory, cardiovascular or other major organ systems, or serious infection, tuberculosis, hepatitis, haematological abnormality, tumour, severe electrolyte or acid-base disturbance, primary or secondary immunodeficiency, severe psychiatric disease, or any clinically significant abnormal laboratory result judged by the investigator to make participation unsuitable
4. Known allergy or hypersensitivity to any study medication or its ingredients
5. Participation in another drug clinical trial currently or within the previous 4 weeks
6. Use of Chinese medicine or topical psoriasis treatments within 2 weeks before enrolment; oral systemic therapy or ultraviolet phototherapy within 4 weeks; or biologic therapy within 5 half-lives before enrolment
7. Any other condition judged by the investigator to make the participant unsuitable for the study

Date of first enrolment

23/12/2024

Date of final enrolment
07/11/2027

Locations

Countries of recruitment
China

Study participating centre
Guangdong Provincial Hospital of Chinese Medicine
No. 111 Dade Road, Yuexiu District
Guangzhou
China
510120

Sponsor information

Organisation
Guangdong Provincial Hospital of Traditional Chinese Medicine

ROR
https://ror.org/01gb3y148

Funder(s)

Funder type

Funder Name
Guangdong Provincial Hospital of Traditional Chinese Medicine

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available