Real-World Evaluation of Secukinumab in Moderate-to-Severe Hidradenitis Suppurativa

2025-06-30

Ethics Approval No. I-24PJ1844

Study Design

This single-center, prospective, observational study aimed to evaluate the efficacy and safety of Secukinumab in treating moderate-to-severe hidradenitis suppurativa (HS). The study was conducted from June 1, 2025, to June 1, 2026, and all participants were treated at the Department of Dermatology, Peking Union Medical College Hospital. The study was approved by the Clinical and Research Ethics Committee of the Chinese Academy of Medical Sciences, Peking Union Medical College Hospital (Ethics Approval No. I-24PJ1844). All procedures involving human participants adhered to the Declaration of Helsinki. Written informed consent form was signed and obtained from the participant.

Patient Selection

Participants were included based on the following criteria: age ≥18 years, diagnosis of moderate-to-severe HS with Hurley stage II or III, Disease duration of ≥6 months, presence of at least one draining tunnel or two inflammatory nodules, inadequate response to prior treatments, such as antibiotics, isotretinoin, or TNF inhibitors. Patients were excluded if they: active infections (e.g., viral hepatitis, active tuberculosis), use of other biologics or systemic immunosuppressants within the past three months, severe organ dysfunction (e.g., hepatic or renal failure), any other conditions that might affect study results. All participants provided informed consent after being fully briefed on the study's objectives and potential risks.

Treatment Regimen

Patients received secukinumab 300 mg weekly for five weeks, followed by 300 mg monthly subcutaneous injection.Depending on their individual presentation, some patients also received concomitant medications, such as isotretinoin, systemic antibiotics (e.g., clarithromycin, minocycline, rifampin), or topical antibiotics. The decision to use concomitant medications, as well as the

specific drug choices and dosages, was based on the patient's clinical needs and physician discretion.

Efficacy and Safety Assessments

Treatment efficacy was evaluated through a comprehensive assessment approach including objective measures and patient-reported outcomes. Disease severity was objectively measured using the International Hidradenitis Suppurativa Severity Score System (IHS4), which quantifies disease activity based on the weighted sum of inflammatory nodules (×1), abscesses (×2), and draining tunnels (dT) (×4), as assessed by the physician. Treatment response was determined using the Hidradenitis Suppurativa Clinical Response 50 (HiSCR50), defined as a ≥50% reduction in the combined count of inflammatory nodules and abscesses from baseline, without an increase in the number of abscesses or draining tunnels at Week 12. During the treatment with secukinumab, the patient also underwent ultrasound assessment and examination. The assessment points were set at baseline, the 4th week, and the 16th week. The evaluation indicators include the regression of nodules and abscesses, the changes in sinus tracts, and the blood flow conditions around the lesion.

Patient-reported outcomes were assessed using three validated instruments: the Pain Numerical Rating Scale (NRS), where patients rated pain intensity from 0 (no pain) to 10 (worst possible pain); the Hidradenitis Suppurativa Quality of Life (HiSQOL) questionnaire, which evaluates the impact of HS on daily life; and the Dermatology Life Quality Index (DLQI), which measures the psychological and quality-of-life impact of skin conditions.

Throughout the study period, adverse events (AEs) were systematically recorded, documenting their symptoms, severity, and duration. All AEs were graded according to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.