

A Study Evaluating the Efficacy of Secukinumab 300mg in Chinese Adults With Active Ankylosing Spondylitis

NCT05303285

Status	RECRUITING
Phase	Phase 4
Sponsor	Tongji Hospital
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (6)

- Participant with a clinical diagnosis of ankylosing spondylitis (AS) and meeting the modified New York criteria for AS.
- Participant must have baseline disease activity as defined by having a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score ≥ 4 and a Patient's Assessment of Total Back Pain score ≥ 4 based on a 0 - 10 numeric rating scale (NRS) at the Screening and Baseline visits.
- Participant has had an inadequate response to at least two nonsteroidal anti-inflammatory drugs (NSAIDs) over an at least 4-week period in total at maximum recommended or tolerated doses, or participant has an intolerance to or contraindication for NSAIDs as defined by the Investigator.
- If entering the study on concomitant methotrexate (MTX), leflunomide, sulfasalazine (SSZ), and/or hydroxychloroquine, participant must be on a stable dose of MTX (≤ 25 mg/week) and/or SSZ (≤ 3 g/day) and/or hydroxychloroquine (≤ 400 mg/day) or leflunomide (≤ 20 mg/day) for at least 28 days prior to the Baseline visit. A combination of up to two background conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) is allowed except the combination of MTX and leflunomide.
- If entering the study on concomitant oral corticosteroids, participant must be on a stable dose of prednisone (≤ 10 mg/day), or oral corticosteroid equivalents, for at least 14 days prior to the Baseline visit.

... and 1 more (see full listing online)

Exclusion (7)

- Prior exposure to any Janus kinase (JAK) inhibitor (including but not limited to tofacitinib, baricitinib, and filgotinib).
- Prior exposure to any biologic therapy with a potential therapeutic impact on spondyloarthritis (SpA).
- Intra-articular joint injections, spinal/paraspinal injection(s), or parenteral administration of corticosteroids within 28 days prior to the Baseline visit. Inhaled or topical corticosteroids are allowed.
- Participant on any other DMARDs (other than those allowed), thalidomide or apremilast within 28 days or five half-lives (whichever is longer) of the drug prior to the Baseline visit.
- Participant on opioid analgesics (except for combination acetaminophen/codeine or acetaminophen/hydrocodone which are allowed) or use of inhaled marijuana within 14 days prior to the Baseline visit.

... and 2 more (see full listing online)

Locations (3 total)

Department of Rheumatology Tongji Hospital, Wuhan, Hubei, China
Tongji Hospital, Wuhan, Hubei, China
Tongji Hospital, Wuhan, Hubei, China

<https://clinicaltrials.gov/study/NCT05303285>

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