Real-world Study on Secukinumab Effectiveness in Biologic-naïve Ankylosing Spondylitis (AS) Patients in Korea.

Last Update: Apr 30, 2025
Real-world Observational Study to Evaluate the Effectiveness of Secukinumab in Biologic-naive Ankylosing Spondylitis Patients in Korea
ClinicalTrials.gov Identifier:
NCT06905288
Novartis Reference Number:CAIN457HKR01
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

This is an observational study to evaluate the effectiveness and safety of secukinumab in participants with AS who have never used TNFi, JAKi, or IL-17i drugs before. This study is an observational study to evaluate the effectiveness and safety of secukinumab in patients with ankylosing spondylitis who are naive to TNFi/JAKi/IL-17i in Korea. Subjects will be recruited from 10 institutions in Korea. The enrollment period is 8 months from the initiation at the first institution and the follow-up periods are 28 weeks(±4 weeks). Data will be gathered at initial visit, 16 weeks(±4 weeks), and 28 weeks(±4 weeks).

Secukinumab is prescribed within the scope of labeling approved in Korea.

Condition
Ankylosing Spondylitis
Overall Status
Recruiting
Number of Participants
70
Start Date
Apr 02, 2025
Completion Date
Jun 30, 2026
Gender
All
Age(s)
18 Years - 40 Years (Adult)

Interventions

Drug

Secukinumab

This is a prospective observational study. There is no treatment allocation. The decision to initiate treatment will be based solely on clinical judgement.

Eligibility Criteria

Inclusion Criteria:

1. Subjects diagnosed with ankylosing spondylitis (AS), as defined by the modified 1984 New York criteria
2. Subjects who have symptoms of active disease at screening and baseline, as evidenced by BASDAI score of ≥ 4
3. Subjects who have never used TNFi, JAKi, or IL-17i drugs before
4. Patients suitable for secukinumab treatment within the scope of labeling by the Ministry of Food and Drug Safety
5. Subjects who have a time of less than 5 years since AS diagnosis
6. Subjects who are above the age of 18 years and below 40years old
7. Subjects who give informed consent form to participate in the study

Exclusion Criteria:

1. Subjects who are in a medical or psychological condition which may prevent them from participating in the study for the study period(28±4 weeks)
2. Subjects who have congenital/traumatic spinal deformities
3. Subjects currently enrolled in other clinical studies
4. Subjects who have any contraindications to secukinumab treatment

Korea, Republic of

Novartis Investigative Site

Recruiting

Busan,49201,Korea, Republic of

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06905288*

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1. https://clinicaltrials.gov/ct2/show/NCT06905288
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