

Study to Evaluate the Pharmacokinetics (PK), Safety and Tolerability up to 6 Years of Intravenous (i.v.) Secukinumab in Pediatric Participants With Juvenile Psoriatic Arthritis (JPsA).

NCT06751238

Status	RECRUITING
Phase	Phase 1
Sponsor	Novartis Pharmaceuticals
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (10)

- Participants parent's or legal representative(s) written informed consent and child's assent, if appropriate, must be obtained before any study related activity or assessment is performed. Of note, if the participant reaches age of consent (as per local law) during the study, they will also need to sign the corresponding study ICF (Informed Consent Form).
 - Males and females e2 years old to \<18 years old at the time of screening.
 - Confirmed diagnosis of JPsA according to the modified International League of Associations for Rheumatology (ILAR) classification criteria that must have occurred at least 6 months prior to screening.
 - Active JPsA disease defined as e3 active joints (swollen or if not swollen must be both tender and limited range of motion) at baseline (BSL).
 - Inadequate response (e1 month) or intolerance to e1 Non-Steroidal Anti-Inflammatory Drug (NSAID) at screening.
- ... and 5 more (see full listing online)

Exclusion (8)

- Participants with body weight less than 10 kg at screening.
 - Use of other investigational drugs within 4 weeks or 5 half-lives of BSL, or until the expected pharmacodynamic effect has returned to BSL, whichever is longer.
 - History of hypersensitivity to study drug or its excipients or to drugs of similar chemical classes.
 - Participants with active inflammatory bowel disease or active uveitis at screening or BSL.
 - Fulfilling diagnostic criteria for any International League of Associations for Rheumatology (ILAR) juvenile idiopathic arthritis (JIA) category other than JPsA at BSL.
- ... and 3 more (see full listing online)

Locations (7 total)

University of Florida, Gainesville, Florida, United States
Ann and Robert H Lurie Childs Hosp, Chicago, Illinois, United States
Levine Childrens Hospital, Charlotte, North Carolina, United States
... and 4 more locations

<https://clinicaltrials.gov/study/NCT06751238>

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