

# Study of Oral Upadacitinib and Subcutaneous/Intravenous Tocilizumab to Evaluate Change in Disease Activity, Adverse Events and How Drug Moves Through the Body of Pediatric and Adolescent Participants With Active Systemic Juvenile Idiopathic Arthritis.

NCT05609630

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Status	RECRUITING
Phase	Phase 3
Sponsor	AbbVie
Enrollment	90 participants

## Key Eligibility Criteria

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### Inclusion (5)

- \- Baseline with a total body weight of 10 kg or higher at screening and symptoms of systemic juvenile idiopathic arthritis (sJIA) according to International League of Associations for Rheumatology (ILAR) criteria for at least 6 weeks prior to Screening, with onset prior to 16 years old, and meet the following conditions:
- Must have active sJIA with at least 2 active joints at Screening and Baseline, fever more than 38°C on at least one day within 14 consecutive days before the Screening Visit, and an erythrocyte sedimentation rate (ESR) or high-sensitivity C-reactive protein (hsCRP) \> upper limit of normal (ULN) at Screening. OR At least 4 active joints at Screening and Baseline and an ESR or hsCRP \> ULN at Screening.
- Must have inadequate response to previous treatment with nonsteroidal anti-inflammatory drugs and/or systemic glucocorticoids, as judged by the investigator.
- For Cohort 1, participants must not have had previous treatment with any IL-6 inhibitor. For Cohort 2, participants must have an intolerance or inadequate response to an IL-6 inhibitor as judged by the investigator.
- Note: For Cohort 1, participants must be ages 2 to \< 18 years old in countries where SC tocilizumab is not approved for sJIA.

### Exclusion (2)

- Has any type of juvenile idiopathic arthritis (JIA), other than sJIA, as defined by the ILAR criteria, and must not have a history or presence of any other autoimmune inflammatory condition other than sJIA.
- Has uncontrolled severe systemic disease and/or impeding or active macrophage activation syndrome within 1 month prior to Baseline.

## Locations (44 total)

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Phoenix Children's Hospital /ID# 253403, Phoenix, Arizona, United States  
Childrens National Medical Center /ID# 253344, Washington D.C., District of Columbia, United States  
New York Medical College /ID# 253437, Valhalla, New York, United States  
... and 41 more locations