

Dupilumab in the Treatment of Pediatric Alopecia Areata

NCT05866562

Status	RECRUITING
Phase	Phase 2
Sponsor	Icahn School of Medicine at Mount Sinai
Enrollment	76 participants

Key Eligibility Criteria

Inclusion (8)

- Male or female participants who are at least 6 years old and under 18 years old, who can provide assent (if appropriate), and for whom signed informed consent can be provided by parent or legal guardian prior to participation in any study assessments or procedures
- -- Participant is able to adhere to the study visit schedule and other protocol requirements.
- Females of childbearing potential (FCBP) must have a negative pregnancy test at Screening and Baseline. While on investigational product and for at least 28 days after taking the last dose of investigational product (IP), FCBP who engage in activity in which conception is possible must use one of the approved contraceptive options described below:
 - Option 1: Any one of the following highly effective methods: hormonal contraception (oral, injection, implant, transdermal patch, vaginal ring); intrauterine device (IUD); tubal ligation; or partner's vasectomy; OR
 - Option 2: Male or female condom (latex condom or non-latex condom NOT made out of natural [animal] membrane [for example, polyurethane]);
- ... and 3 more (see full listing online)

Exclusion (16)

- Inability or unwillingness of a participant to give written informed consent or comply with study protocol
- Participant is pregnant or breastfeeding.
- Participant's cause of hair loss is indeterminable and/or they have concomitant causes of alopecia, such traction, cicatricial, pregnancy-related, drug-induced, telogen effluvium, or advanced androgenetic alopecia (i.e. Ludwig Type III or Norwood-Hamilton Stage e V).
- Participant has a history of AA with no evidence of hair regrowth for e 7 years since their last episode of hair loss.
- Severe, uncontrolled asthma (having 2 or exacerbations in the last 12 months that require systemic steroids and/or hospitalization) or a history of life-threatening asthma exacerbations while on appropriate anti-asthmatic medications.
- ... and 11 more (see full listing online)

Locations (5 total)

University of California, Irvine, Irvine, California, United States
University of California San Diego, San Diego, California, United States
Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, Illinois, United States
... and 2 more locations

<https://clinicaltrials.gov/study/NCT05866562>

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