A study of growth, development and maturation in adolescents with atopic dermatitis who receive upadacitinib

First published: 22/08/2023

Last updated: 09/01/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS106180

Study ID

106181

DARWIN EU® study

No

Study countries

- [ ] Canada
- [ ] France
- [ ] Germany
- [ ] Latvia

- [ ] Spain
- [ ] Türkiye
- [ ] United States

Study description

This will be an observational, prospective cohort study of adolescents who receive upadacitinib or biologic or other non-biologic, non-JAKi systemic therapies approved for the treatment of moderate to severe AD at the time of registry enrollment.

Study status

Ongoing

Contact details

Study institution contact

Clinical Trial Disclosure AbbVie CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Clinical Trial Disclosure AbbVie

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 22/03/2021

Study start date
Planned: 15/11/2023

Actual: 20/12/2023

Date of final study report
Planned: 31/12/2033

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

P21-824_Protocol_Abstract_Redacted.pdf(233.49 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

To evaluate the growth, development and maturation in North American (US and Canada) [NA]-residing adolescents with moderate to severe Atopic Dermatitis who receive upadacitinib versus comparator medications. If feasible, a cohort of European residing adolescents with moderate to severe AD will also be evaluated.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

RINVOQ

Study drug International non-proprietary name (INN) or common name

UPADACITINIB

Anatomical Therapeutic Chemical (ATC) code

(L04AA44) upadacitinib

upadacitinib

Medical condition to be studied

Dermatitis atopic

Population studied

Age groups

Adolescents (12 to < 18 years)

Estimated number of subjects

700

Study design details

Outcomes

(1) compare changes from baseline in height and weight standard deviation score, (2) compare somatic maturity timing measured by age at peak height velocity, (3) compare changes from baseline in pubertal progression as measured by Tanner stage, and (4) compare the incidence rates of bone

fractures in adolescents with moderate to severe AD treated with upadacitinib and comparator medications. The secondary objectives of the study are to describe changes from baseline in standing height, height percentiles, height velocity, height velocity SDS, weight, weight percentiles, body mass index (BMI), BMI percentiles, and BMI SDS, as well as the frequency of delayed puberty in adolescents with moderate to severe AD treated with upadacitinib and comparator medications.

Data analysis plan

Primary Analysis: For each exposure cohort for the primary analyses, patient characteristics at baseline, including demographics, clinical and disease characteristics, treatment history, and patient reported outcomes will be described. Descriptive summary statistics will be provided for each study outcome. Changes for growth-related measures from baseline to end of follow-up will be described overall for all adolescents and by exposure cohort, including changes in height SDS and weight SDS. Age at peak height velocity (PHV), incidence of bone fractures during the follow-up period will be described by exposure cohort. Propensity score methods will be used to account for differences between exposure cohorts at baseline. Changes in height SDS, changes in weight SDS, age at PHV, age at Tanner stage progression, and incidence of bone fractures will be compared between the two propensity score trimmed exposure cohorts from North America. Refer to protocol abstract for secondary analysis.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes