# 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

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**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

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**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

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**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

**Medicinal product name**

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.

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**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

# ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## 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