

# An Observational Post-authorization Safety Study of Ustekinumab in the Treatment of Pediatric Patients Aged 6 Years and Older With Moderate to Severe Plaque Psoriasis

**First published:** 13/06/2017

**Last updated:** 14/03/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS19506

### Study ID

41293

### DARWIN EU® study

No

### Study countries

- Austria
- Belgium
- Denmark

- France
- Greece
- Netherlands
- Norway
- Russian Federation
- Switzerland
- United Kingdom

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### **Study description**

This study aims to monitor the long-term safety, growth and development in pediatric patients (aged 6 years to 18 years) with moderate to severe plaque psoriasis who receive ustekinumab treatment. Primary objective: monitor the long-term safety of ustekinumab in pediatric patients (aged 6 years to 18 years) with moderate to severe plaque psoriasis, through monitoring for the following adverse events potentially related to immune modulation: serious infections, malignancies and autoimmunity, monitor the long-term effects of ustekinumab on growth (weight, height, body mass index) and development (sexual maturity based on the Tanner Scale). Secondary objectives: monitor clinical outcomes (PASI, PGA, and BSA), patient-reported quality of life CDLQI, and comorbidities in pediatric patients with moderate to severe plaque psoriasis treated with ustekinumab.

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### **Study status**

Ongoing

## Research institutions and networks

### Institutions

# Radboud university medical center (Radboudumc)

Netherlands

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**Institution**

**Educational Institution**

**Hospital/Clinic/Other health care facility**

**ENCePP partner**

## Contact details

### **Study institution contact**

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**Study contact**

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### **Primary lead investigator**

Ahlem Azzabi

**Primary lead investigator**

## Study timelines

### **Date when funding contract was signed**

Planned: 01/09/2017

Actual: 07/09/2016

**Study start date**

Planned: 15/09/2017

Actual: 28/10/2017

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**Date of final study report**

Planned: 31/03/2033

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Janssen Pharmaceutica NV

## 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)

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

**Main study objective:**

To monitor the long-term safety of ustekinumab in pediatric patients with moderate to severe plaque psoriasis, through monitoring for the following adverse events potentially related to immune modulation: serious infections, malignancies and autoimmunity. To monitor the long-term effects of ustekinumab on growth (height, weight, BMI) and development (sexual maturity based on the Tanner scale).

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Prospective observational post-marketing authorization

## Study drug and medical condition

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

USTEKINUMAB

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## **Anatomical Therapeutic Chemical (ATC) code**

(L04AC05) ustekinumab

ustekinumab

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## **Medical condition to be studied**

Psoriasis

## **Population studied**

### **Age groups**

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

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### **Estimated number of subjects**

135

## **Study design details**

### **Outcomes**

Long-term safety of ustekinumab in pediatric patients with moderate to severe plaque psoriasis, through monitoring for the following adverse events potentially related to immune modulation: serious infections, malignancies and autoimmunity. Long-term effects of ustekinumab on growth (height, weight, BMI) and development (sexual maturity based on the Tanner scale). Clinical outcomes (PASI, PGA, BSA), quality of life CDLQI, and comorbidities in pediatric patients with moderate to severe plaque psoriasis treated with ustekinumab.

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### **Data analysis plan**

Data from the study will be evaluated using a longitudinal observational inception cohort to monitor safety and tolerability, clinical outcomes, quality of life, comorbidities, and treatment regimens. The clinical outcomes of patients with different burdens of disease and/or treatment modalities will also be evaluated. No formal hypothesis testing is planned. Appropriate descriptive statistics will be used to summarize data including medical history, disease characteristics, prior and concomitant psoriasis therapies, and clinical outcomes. Incidences of adverse events in patients who have received ustekinumab will be collected and analyzed. The primary analysis will include all ustekinumab-exposed patients. Subgroup analyses will be performed by age category on patients with age at start of data collection (initiation of ustekinumab treatment)  $\geq 12$  years to  $< 18$  years, and on patients with age at start of data collection  $\geq 6$  years to  $< 12$  years.

## 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

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**Data sources (types), other**

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

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## Data characterisation

**Data characterisation conducted**

No