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

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## 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	

#### 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.

### Study status

Ongoing

Research institutions and networks

**Institutions** 

Radboud university medical center (Radboudumc)		
☐ Netherlands		
First published: 30/06/2022		
Last updated: 21/03/2025		
Institution Educational Institution Hospital/Clinic/Other health care facility		
ENCePP partner		

## Contact details

### **Study institution contact**

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Study contact

RA-RNDUS-ClnclTrlsEU@its.jnj.com

### 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

#### 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

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

#### 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

#### 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

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

(L04AC05) ustekinumab ustekinumab

#### Medical condition to be studied

**Psoriasis** 

## Population studied

#### Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

#### **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.

#### **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

### 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

### **Check completeness**

Unknown

### **Check stability**

Unknown

### **Check logical consistency**

Unknown

## Data characterisation

#### **Data characterisation conducted**

No