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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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

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

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Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Contact details

Study institution contact

Ahlem Azzabi RA-RNDUS-ClnclTrlsEU@its.jnj.com

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) ≥12 years to <18 years, and on patients with age at start of data collection ≥6 years to <12 years.

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

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No