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: 02/07/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/41293

EU PAS number
EUPAS19506

Study ID
41293

DARWIN EU® study
No

Study countries
Austria
Belgium
Denmark
France
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 institution and networks

Institutions

Radboud University Medical Center (Radboudumc)
Netherlands
First published: 01/02/2024
Last updated 17/04/2024
Institution

Contact details

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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

Medical condition to be studied
Psoriasis

Population studied

Age groups
Children (2 to < 12 years)
Adolescents (12 to < 18 years)

Estimated number of subjects
105

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