Real World Evidence of Safety and Dosing of Mircera in Children with Chronic Kidney Disease

First published: 26/02/2019

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS28490

Study ID

44502

DARWIN EU® study

No

Study countries

Germany

Study description

The study aims to further characterize safety, dosing and related hemoglobin concentrations and to validate the dose simulation models of Mircera in pediatric patients with anemia due to CKD in a real-world setting.

Study status

Finalised

Research institutions and networks

Networks

International Pediatric Dialysis Network (IPDN)

European Union

First published: 28/12/2020

Last updated: 20/08/2024

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Franz Schaefer

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 22/08/2018

Actual: 22/08/2018

Study start date
Planned: 01/03/2019

Actual: 21/01/2019

Date of interim report, if expected
Planned: 29/11/2019

Actual: 24/10/2019

Date of final study report
Planned: 31/12/2021

Actual: 29/12/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Hoffmann La Roche

Study protocol

Prot MH40258 MIRCERA v1, Published Output-1_21 Jan 2019_Redacted.26.2.19_Redacted Encepp.pdf (3.78 MB)

Prot MH40258 Methoxy Polyethylene Glycol - Epoetin Beta v2, Published Output-1_Redacted.pdf (1.29 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

MH40258

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The objectives for the study are to describe the safety profile of Mircera by aggregate assessment of safety data (number and causes of deaths and hospitalizations) and to assess the relationship between Mircera dosing and Hb concentrations using patient level data.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Non-interventional study secondary data use (NIS SDU) and voluntary post-authorization safety study (PASS) of pediatric patients from the International Pediatric Peritoneal Network (IPPN) and International Pediatric Hemodialysis

Network (IPHN)

Study drug and medical condition

Medicinal product name

MIRCERA

Medical condition to be studied

Chronic kidney disease

Population studied

Short description of the study population

Pediatric patients aged from 0 months to less than 18 years old on chronic peritoneal dialysis (PD) or HD, with at least one observation while treated with Mircera, who are included in two international, prospective, multicenter registries (IPPN and IPHN).

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)
- Infants and toddlers (28 days – 23 months)
- Term newborn infants (0 – 27 days)

Special population of interest

Renal impaired

Estimated number of subjects

148

Study design details

Outcomes

Descriptive analyses of aggregate safety data for the cumulative number and leading cause of hospitalizations and deaths, over the period of observation (patients on Mircera treatment in the registry) and until 6 months after the last observation. Descriptive analysis of the relationship between Mircera dose and Hb concentrations using patient level data at the first and subsequent observations. An external validation of the Modeling and Simulation Framework will be performed and compared to observed data from the present study. The dose conversions from previous ESA treatment to Mircera will be evaluated.

Data analysis plan

The primary objectives will be addressed by conducting descriptive analyses for aggregate safety data, including cumulative number and cause of hospitalizations and deaths over the observation period and until 6 months after the last observation on Mircera and for patient level data on Mircera dose and Hb concentration at the first and subsequent observation(s) under Mircera treatment. Patient characteristics to be evaluated include demographics, clinical characteristics, specific treatments, and laboratory measures within each registry (IPPN and IPHN) for each age group. The secondary objectives will be addressed by conducting an external validation of the Modeling and Simulation Framework for Mircera that has been developed on Phase II and III adult data and the first pediatric study DOLPHIN (NH19707, Fischbach et al. 2018). In addition, the dose conversions from previous ESA treatment to Mircera that were determined/tested in studies NH19707 (IV) and NH19708 (SC) will be evaluated.

Documents

Study results

1113174-csr-mh40258-CSR_synopsis_Redacted.pdf (183.84 KB)

Data management

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

IPDN (entertains two registries): The IPPN registry for children on chronic peritoneal dialysis, and the IPHN registry for children on hemodialysis http://pedpd.org/

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