A post-authorisation safety study (PASS) to describe real-world safety and effectiveness of NUCALA (mepolizumab) in paediatric eosinophilic granulomatosis with polyangiitis (EGPA) patients in Europe (218065)

First published: 03/11/2022

Last updated: 09/08/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS49460

Study ID

49461

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Spain
- [ ] United Kingdom

Study description

This multinational, multi-site, case-series will aim to collect data on real-world safety and effectiveness of up to 24 months after the initiation of mepolizumab treatment in paediatric EGPA patients in Europe. In addition, demographic and relevant medical history data will be collected up to 12 months prior to the first dose of mepolizumab.

Study status

Ongoing

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

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Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 18/10/2021

Study start date

Planned: 04/06/2024

Actual: 07/02/2024

Date of final study report

Planned: 25/04/2031

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GSK

Study protocol

49466.pdf(1.29 MB)

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

Disease epidemiology

Effectiveness study (incl. comparative)

Main study objective:

The primary objective of this study is to describe the real-world safety of mepolizumab treatment in paediatric EGPA patients aged 6 to 17 years in terms

of AEs, SAEs, pregnancy exposures and medical device incidents.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-series

Study drug and medical condition

Name of medicine

NUCALA

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

MEPOLIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(R03DX09) mepolizumab

mepolizumab

Medical condition to be studied

Eosinophilic granulomatosis with polyangiitis

Population studied

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Estimated number of subjects

10

Study design details

Data analysis plan

Data from this study will be described per patient as a case series, as the sample size will be insufficient to perform statistical analyses or summarise across patients.

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