Nucala Subcutaneous Injection Special Drug Use Investigation (Long-Term) (204524)

First published: 22/02/2017

Last updated: 22/05/2024

Study Finalised

Administrative details

EU PAS number

EUPAS17926

Study ID

38541

DARWIN EU® study

No

Study countries

☐ Japan

Study description

This investigation is conducted to collect and evaluate information on safety and effectiveness of long term use of Nucala subcutaneous injection in Asthma patients in daily clinical practice.

Study status

Finalised

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

Planned: 15/04/2016

Actual: 15/04/2016

Study start date

Planned: 31/01/2018

Actual: 11/01/2017

Date of final study report

Planned: 27/06/2024

Actual: 14/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-204524-protocol-redact.pdf(216.61 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

This investigation is conducted to collect and evaluate information on safety and effectiveness of long term use of Nucala subcutaneous injection in Asthma patients in daily clinical practice.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational Post Marketing Surveillance under actual drug use condition

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

Asthma

Population studied

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

1000

Study design details

Outcomes

Information on safety and effectiveness of Nucala subcutaneous injection in daily clinical practice.

Data analysis plan

Safety: The incidence of ADRs and 95% confidence interval will be calculated.
Effectiveness: The response rate based on the global assessment of effectiveness and its 95% confidence interval will be calculated. For comparison of the scores, etc. the summary statistics for values at the time of measurement and changes from baseline will be calculated.
Consideration of covariates: The covariate that affects safety (incidence of ADRs) and effectiveness (response rate) will be considered by calculating the odds ratio and its 95% confidence interval.

Documents

Study report

gsk-clinical-study-report-Anonymized 08 May 2024.pdf(2.59 MB)

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