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

First published: 22/02/2017
Last updated: 22/05/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/38541

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 institution and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor

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 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:
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

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