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

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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)

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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 typo

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

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

Other	(types)				
Data sources	(types), othe	r			
Prospective pa	ient-based dat	a collectio	n		
Use of a (Common	Data N	Model (CDM)	
CDM mapping					
No					
Data qua	ity spacit	fication	2.5		
Data qua	ity specii	icatioi	15		
Check confor		icatioi	15		
•		icatioi	15		
Check confor	nance	icatioi	15		
Check confor	nance	icatioi	15		
Check conford Unknown Check comple	nance teness	icatioi	15		

Data characterisation

Data characterisation conducted

No