Post-authorisation safety study of the incidence rate of medication errors before and after the discontinuation of the lower strength vials for Pharmalgen (NI-PH-X-01)

First published: 21/09/2018

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS25639

Study ID

30408

DARWIN EU® study

No

Study countries

Denmark

United Kingdom

Study description

ALK has discontinued production of the lower strengths ofPharmalgen (0.12 µg, 1.2 µg and 12 µg, lower strength vials).Removal of the lower strength vials from the market necessitates achange in the preparation of the up-dosing strengths. The purpose of this study is to characterize safety of Pharmalgenproducts after removal of the lower strength vials to evaluate if anincrease occurs in medication errors or systemic allergic reactionsrelated to medication errors during the up-dosing phase. The data collected for this study will be spontaneously reportedindividual case safety reports (ICSRs) of medication errors andserious systemic allergic reactions concerning patients in the up-dosing phase of treatment with Pharmalgen (801) Apis mellifera orPharmalgen (802) Vespula spp. from the UK.

Study status

Finalised

Research institutions and networks

Institutions

ALK-Abelló

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Institution

Contact details

Study institution contact

Holst Andreas DKHOQPPV@alk.net

Study contact

DKHOQPPV@alk.net

Primary lead investigator

Holst Andreas

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/05/2017

Actual: 02/05/2017

Study start date

Planned: 01/01/2017

Actual: 01/01/2017

Data analysis start date

Planned: 01/01/2019

Actual: 01/01/2019

Date of final study report

Planned: 30/06/2019

Actual: 13/05/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ALK-Abelló A/S

Study protocol

PASS protocol Pharmalgen_final.pdf (710.18 KB)

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

The purpose of this study is to characterize safety of Pharmalgenproducts after removal of the lower strength vials previously used to prepared doses for up-dosing to evaluate if an increase occurs in medication errors or systemic allergic reactions related to medication errors during the up-dosing phase.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective descriptive case study

Study drug and medical condition

Medicinal product name, other

Pharmalgen

Population studied

Short description of the study population

Patient who initiates immunotherapy treatment with either Pharmalgen (801) Apis mellifera or Pharmalgen (802) Vespula spp.

Age groups

- Children (2 to < 12 years)
- 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)

Estimated number of subjects

231

Study design details

Data analysis plan

The number of medication errors and serious systemic allergicreactions related to medication errors will be recorded in the studyperiod and the rate calculated as number of cases divided bynumber of treatment years. Exact 95% binomial confidenceintervals for the calculated rate will be reported.

Documents

Study results

Pharmalgen PASS summary_final.pdf (24.84 KB)

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

Unknown