Post-Market Claims-Based Study of Allergic Reactions and Eosinophilic Esophagitis in Marketed Use of GRASTEK? in the United States (MK-7243-025)

First published: 13/01/2017

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/25093

EU PAS number

EUPAS17245

Study ID

25093

DARWIN EU® study

No

Study countries

United States

Study description

The purpose of this study is to estimate the incidence of serious allergic reactions and eosinophilic esophagitis (EoE) in participants exposed to GRASTEK in a large, United States (US)-based, commercially insured population. The study objectives are to: 1) Describe characteristics of participants using GRASTEK with respect to demographics, concomitantmedications and co-morbidities, 2) Estimate the incidence of serious allergic reactions in participants newly receiving GRASTEK resulting in hospitalization, emergency department care or epinephrine injection in the ambulatory setting, 3) Estimate the incidence of EoE in participants newly receiving GRASTEK, and 4) Conduct an analysis of exposed participants to describe potential baseline risk factors for serious allergic reactions and EoE.

Study status

Ongoing

Research institutions and networks

Institutions

ALK-Abelló

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Institution

Contact details

Study institution contact

GCD ALK

Study contact

ClinicalTrials@alk.net

Primary lead investigator

Riis Bente

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/06/2015

Actual: 28/08/2014

Study start date

Planned: 30/09/2016

Actual: 19/05/2016

Date of final study report

Planned: 30/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ALK-Abelló A/S

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

Main study objective:

To further describe the safety profile of GRASTEK in marketed use in the US and to monitor the incidence of serious allergic reactions and EoE in participants using GRASTEK.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Case-series

Study drug and medical condition

Medical condition to be studied

Anaphylactic reaction

Eosinophilic oesophagitis

Population studied

Age groups

Infants and toddlers (28 days – 23 months)

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

10000

Study design details

Outcomes

Describe the characteristics of participants initiating GRASTEK (demographics, concomitant medications, co-morbidities).Estimate the incidences of the following in participants newly receiving GRASTEK: 1) serious allergic reactions and 2) EoE.Conduct an analysis of exposed participants to describe potential baseline risk factors for serious allergic reactions and EoE.

Data analysis plan

Participants treated with GRASTEK and participants experiencing events of interest will be described according to all available demographic characteristics, prescription medications, co-morbidities and characteristics of GRASTEK treatment. For each of the two end points (serious allergic reactions and cases of EoE), multivariate models will be constructed using confirmed cases as the dependent variable and various baseline factors as potential independent variables among new users. Results of case series analyses will be presented as estimates of rate ratios and 95% confidence intervals for each identified risk factor.

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

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