Post-Market Claims-Based Study of Serious Allergic Reactions and Eosinophilic Esophagitis in Marketed Use of RAGWITEK? in the United States (MK-3641-010)

First published: 13/01/2017

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Study Ongoing

Administrative details

EU PAS number

EUPAS17248

Study ID

25096

DARWIN EU® study

No

Study countries

☐ United States

Study description

The purpose of this study is to estimate the incidence of serious allergic events and eosinophilic esophagitis in participants exposed to RAGWITEK? in usual care. The objectives of this study are to: 1) Describe characteristics of participants initiating RAGWITEK withrespect to demographics, concomitant medications and co-morbidities, 2) Estimate the incidence of serious allergic reactions in participants newly receiving RAGWITEK resulting in hospitalization, emergency department care or epinephrine injection in the ambulatorysetting, 3) Estimate the incidence of eosinophilic esophagitis (EoE) in participants newly receiving RAGWITEK, and 4) Conduct an analysis of exposed participants to describe potential baseline risk factors for serious allergic events or EoE.

Study status

Ongoing

Research institutions and networks

Institutions

ALK-Abelló

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Institution

Contact details

Study institution contact

Riis Bente ClinicalTrials@alk.net

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 RAGWITEK in marketed use in the United States and to monitor the incidence of serious allergic reactions and EoE in participants using RAGWITEK

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

To describe the characterisitics of participants initiating RAGWITEK with respect to demographics, concomitant medications and co-morbidities.To estimate the incidences of: 1) serious allergic reactions resulting in hospitalization, emergency department care or epinephrine injection in the ambulatory setting and 2) EoE, in participants newly receiving RAGWITEK.

Data analysis plan

Participants treated with RAGWITEK and participants experiencing events of interest will be described according to all available demographic characteristics, presecription medications, comorbidities and characteristics of RAGWITEK 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