# 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

**Last updated:** 03/08/2018

Study Ongoing

## Administrative details

**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

**First published:** 01/02/2024

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**Institution**

# Contact details

**Study institution contact**

GCD ALK 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

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**Study start date**

Planned: 30/09/2016

Actual: 19/05/2016

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**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

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**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

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**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**

10.000

# 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.

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**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

## 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)**

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