Survey on the knowledge and use of the Jext prescriber’s checklist among physicians – a post-authorisation safety study (XX-JX-01)

First published: 05/04/2019

Last updated: 02/01/2020

Study Finalised

Administrative details

EU PAS number

EUPAS29289

Study ID

32970

DARWIN EU® study

No

Study countries

Ireland

Study status

Finalised

Research institutions and networks

Institutions

ALK-Abelló

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Andreas Slyngborg Holst ahtit@alk.net

Study contact

ahtit@alk.net

Primary lead investigator

Andreas Slyngborg Holst

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 18/12/2018

Study start date

Planned: 01/06/2019

Actual: 11/04/2019

Data analysis start date
Actual: 26/06/2019

Date of final study report
Planned: 01/12/2019

Actual: 17/09/2019

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?

No

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:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The Jext prescriber’s checklist constitutes a risk minimisation measure (RMM) for Jext, and is included in the Jext risk management plan. As a consequence, effectiveness of the RMM should be evaluated following its implementation into the market. The objective of this study is to assess the effectiveness of the implementation of the Jext prescriber’s checklist.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post authorization study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C01CA24) epinephrine

epinephrine

Population studied

Short description of the study population

Physicians who has received Jext prescriber’s checklist.

Age groups

- 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

50

Study design details

Outcomes

To assess the effectiveness of the implementation of the Jext prescriber’s checklist.

Data analysis plan

Data analysis stage will consist of preparing the total tally of responses for each question posed. In addition, cross tabulations will be prepared for all survey questions against various sub-groups, e.g. physician types, caseloads and

practice setting. In addition to the responses to the questions of the main questionnaire, the number of respondents who have prescribed Jext, but are not familiar with the prescriber’s checklist, will be calculated.

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

Data collection from panel of physicians

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