Evaluation of the Safety and Effectiveness of BOTOX® Injection 50 Units (ClostridiumBotulinum Toxin Type A) for the Treatment of Patients with Moderate to Severe Lateral Canthal Lines (Crow’s Feet Lines) With or Without Simultaneous Glabellar Lines Treatment:A Postmarketing Surveillance Study in Korea

First published: 08/11/2016

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS16150

Study ID

34190

DARWIN EU® study

No

Study countries

Korea, Democratic People's Republic of

Study description

The purpose of this prospective, observational postmarketing surveillance (PMS) study is to evaluate the safety and effectiveness of BOTOX® for the treatment of patients with moderate to severe lateral canthal lines (crow’s feet lines) as required by the Korea Ministry of Food and Drug Safety (MFDS). The study will be conducted in at least 600 adult (18 to 75 years of age) Korean patients who are treated with BOTOX injection from a 50 units (U) vial at the labeled dose for crow’s feet lines only (BOTOX 24 U) or crow’s feet lines and glabellar lines simultaneously (BOTOX 24 U for crow’s feet lines) as per clinical practice. Each patient will have one follow-up contact within 3 months of the BOTOX treatment to collect safety and effectiveness data on crow’s feet lines. The study will sequentially enroll eligible Korean patients treated with BOTOX, with a signed private information protection act form or informed consent form (ICF), at each of the selected clinic(s)/hospital(s) from the date of contract until at least 600 patients have completed one follow-up contact during the study period. The decision to treat a patient with BOTOX is determined by the physician and patient prior to the decision to include the patient in the study. Safety information and effectiveness as assessed by the investigator and by the patient will be collected during any in-office visit within 3 months of the index BOTOX treatment or before receiving a new BOTOX treatment if the new treatment occurs within 3 months. Safety information and the patient’s assessment of effectiveness may also be collected via telephone contact if patients do not have an in-office visit during this 3-month period. The investigator’s assessment of effectiveness will not be collected over the telephone. The analyses will be descriptive in nature. The study will be

completed within 4 years after product/indication approval Periodic and final reports will be sent to the MFDS.

Study status

Finalised

Research institutions and networks

Institutions

DreamCIS

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Institution

Contact details

Study institution contact

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Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Anita Verga

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 20/05/2014

Actual: 25/08/2014

Study start date
Planned: 30/09/2014

Actual: 30/09/2014

Date of final study report
Planned: 03/05/2018

Actual: 02/05/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Allergan

Study protocol

191622-147 Protocol_ENGL.Redacted (2).pdf (506.61 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Non-EU RMP only

Other study registration identification numbers and links

191622-147

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

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The purpose of this postmarketing surveillance (PMS) study is to evaluate the safety and effectiveness of BOTOX for the treatment of patients with moderate to severe crow’s feet lines through active surveillance under routine clinical practice

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, observational postmarketing surveillance (PMS)

Study drug and medical condition

Medicinal product name, other

Botox

Population studied

Short description of the study population

Adult Korean patients, 18 to 75 years of age, inclusive, treated with BOTOX for moderate to severe crow’s feet lines only or for crow’s feet lines and glabellar lines simultaneously according to the approved label.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Estimated number of subjects

600

Study design details

Outcomes

All adverse events that occur during the index BOTOX administration and/or during the follow-up period after BOTOX administration, Investigators rating of improvement in appearance of crow's feet lines (improved, unchanged, or worsened) during follow-up visits. Patient's assessment of the change in the appearance of crow’s feet lines compared with the appearance before the index BOTOX treatment (very much improved, much improved, minimally improved, no change, minimally worse, much worse or very much worse)

Data analysis plan

Categorical variables (eg, gender) will be summarized by the number and percentage of patients in each category. Any missing category included in the CRF or generated from data collection will be treated as an independent category without imputation. For describing the incidence of adverse events, the frequency, patient-time incidence rate, and 95% CI for the incidence measures will be displayed. Unless otherwise specified, the 95% CI of the proportions will be calculated using the exact method, and the 95% CI of the incidence rates will be constructed assuming the frequency of a particular event in a given period of time follows a Poisson distribution. Continuous variables (eg, age) will be summarized using descriptive statistics (number of non-

missing values, mean, standard deviation, median, minimum, and maximum values). Additional exploratory descriptive and inferential analyses of the data will be conducted as deemed appropriate.

Documents

Study results

BOTOX_CFL_Re-RPT_dV1.0_Eng_(20180502)_Redacted_29_Jun_2018.pdf (1.29 MB)

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

No