

# Evaluation of the Safety and Effectiveness of BOTOX® Injection 50 Units (Clostridium Botulinum 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

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### Study ID

34190


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**DARWIN EU® study**

No

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## **Study countries**

 Korea, Democratic People's Republic of

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## **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.

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### DreamCIS

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

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Institution

## Contact details

### Study institution contact

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Study contact

[CT.Disclosures@abbvie.com](mailto: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

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## **Study start date**

Planned: 30/09/2014

Actual: 30/09/2014

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## **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

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## 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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**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

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### **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.

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### **Age groups**

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

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### **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)

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## 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](#)

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### 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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No