Evaluation of the Safety and Effectiveness of BOTOX® (Clostridium Botulinum Toxin Type A) in the Treatment of Patients with Urinary Incontinence due to Neurogenic Detrusor Overactivity or Overactive Bladder: A Post-marketing Surveillance Study inKorea

First published: 08/11/2016

Last updated: 20/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS16140

Study ID

34187

DARWIN EU® study

No

Study countries

☐ Korea, Democratic People's Republic of

Study description

Study Objectives The purpose of this PMS study is to evaluate the safety and effectiveness of BOTOX for the treatment of patients with urinary incontinence due to either NDO or OAB through active surveillance under routine clinical practice after the launch of BOTOX in Korea. Study Population Adult patients (≥ 18 years of age) with urinary incontinence due to NDO, e.g. as a result of SCI or MS, or with symptoms of urge urinary incontinence, urgency, and frequency due to OAB who have an inadequate response to or are intolerant of an anticholinergic medication as evaluated and determined by treating physicians Study Sites This study will be mainly conducted by collecting relevant information on treated patients from contracted specialists in the applicable hospitals/clinics. Patient Recruitment The investigators will continuously enroll all eligible patients treated with BOTOX at the relevant hospital(s) to ensure unbiased enrollment of patients during the agreed surveillance period. Study Size Allergan plans to study approximately 600 patients with NDO or OAB who have received BOTOX injection(s) for the treatment of urinary incontinence and other symptoms. Safety Variables All AEs that occur during BOTOX administration and/or after BOTOX administration during the follow-up period will be collected regardless of causal relationship to BOTOX. Effectiveness Variables The International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) instrument will be used to evaluate effectiveness. The ICIQ-SF will be administered to patients before the injection of BOTOX and at the next office visit within 1 to 4 months after injection of BOTOX. The evaluation will be based on the change in the total score before and after administration of the BOTOX (ICIQ Score change = post-injection ICIQ score – pre-injection ICIQ score). Duration The study should be completed within 4 years after approval Analysis The analyses will be descriptive in nature.

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

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Primary lead investigator

Anita Verga

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 24/09/2013

Study start date
Planned: 30/01/2014

Actual: 05/02/2014

Date of final study report
Planned: 30/12/2016

Actual: 30/11/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Allergan

Study protocol

(Korea) Botox in NDO NOV2013.pdf(693.4 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

Methodological aspects

Study type

Study topic:

Disease /health condition

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:

To evaluate the safety and effectiveness of BOTOX for the treatment of patients with urinary incontinence due to either NDO or OAB through active surveillance under routine clinical practice after the launch of BOTOX in Korea

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Intensive monitoring schemes, Post-marketing surveillance

Study drug and medical condition

Name of medicine, other

Botox

Medical condition to be studied

Urinary incontinence

Population studied

Short description of the study population

Adult patients (≥ 18 years of age) with urinary incontinence due to neurogenic detrusor overactivity (NDO), e.g., as a result of spinal cord injury (SCI) or multiple sclerosis (MS), or with symptoms of urge urinary incontinence, urgency, and frequency due to OAB who have an inadequate response to or are intolerant of an anticholinergic medication as evaluated and determined by treating physicians.

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)

Special population of interest

Other

Special population of interest, other

Patients with Urinary incontinence

Estimated number of subjects

600

Study design details

Outcomes

All AEs that occur during BOTOX administration and/or after BOTOX administration during the follow-up period, Response to the International Consultation on Incontinence questionnaire Short Form (ICIQ-SF) instrument

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Data analysis plan

Descriptive analyses will be performed to gain an understanding of the qualitative and quantitative nature of the data collected and the characteristics of the sample studied. NDO and OAB patients will be analyzed together, as well as separately. For describing the incidence of adverse events, the frequency, cumulative incidence proportion, patient-year incidence rate, and 95% CI for the cumulative 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

Documents

Study results

BtxNDOOAB_Re-examination report_Eng_V1 0_clean_Final_20161202_Redacted.pdf(4.89 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