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

First published: 08/11/2016

Last updated: 31/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS16153

Study ID

22807

DARWIN EU® study

No

Study countries

India

Study description

Objectives The purpose of this phase IV post-marketing surveillance 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 India. Study Population Adult patients (≥ 18 years of age) with urinary incontinence due to NDO or 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 Contracted specialists in the applicable departments in hospitals and clinics Patient Recruitment All eligible patients treated with BOTOX at the relevant hospital(s) to ensure unbiased enrollment of patients during the agreed surveillance period. Study Size Approximately 250 patients with NDO or OAB who have received BOTOX injection(s) for the treatment of urinary incontinence. Only those patients who have consented to the study by signed Informed Consent Form (ICF) will be included in the study. Follow-up Safety and effectiveness details will be collected during the period from 1 to 4 months after BOTOX treatment. Study Duration 1 year after study start date, however, the actual enrollment status will be communicated to DCGI and if needed, additional time period would be sought. Data Collection Investigators will collect the required information on enrolled patients utilizing Allergan provided case report forms (CRFs) once the contract has been executed. 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 Analysis Only descriptive analyses will be performed.

Study status

Finalised

Research institutions and networks

Institutions

Syneos Health

United Kingdom

First published: 23/04/2015

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Institution | **Non-Pharmaceutical company** | **ENCePP partner**

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: 24/07/2015

Study start date
Planned: 19/10/2015

Actual: 16/12/2015

Date of final study report
Planned: 03/02/2018

Actual: 31/01/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Allergan

Study protocol

191622-140 Protocol v2013-05-06 (002).REDACTED.pdf (388.22 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

191622-140

Methodological aspects

Study type

Study type list

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 India.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Botox

Medical condition to be studied

Incontinence

Population studied

Short description of the study population

Adult patients (≥ 18 years of age) with urinary incontinence due to neurogenic detrusor overactivity , eg, as a result of spinal cord injury or multiiple sclerosis, or due to overactive bladder 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)

Estimated number of subjects

250

Study design details

Outcomes

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, 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.

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. Categorical variables (eg, gender) will be summarized by the number and percentage (%) of patients in each category. 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 Continuous variables (eg, age) will be summarized using descriptive statistics (number of non-missing values, mean, standard deviation, median, minimum and maximum values).

Documents

Study results

191622-140 (NDO in India) Abstract.pdf (42 KB)

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

Unknown