Drug Use Result Survey of Botox Vista® Injection 50 Units

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Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/30867

EU PAS number
EUPAS16104

Study ID
30867

DARWIN EU® study
No

Study countries
Japan

Study description
Objective The purpose of this survey is to collect and evaluate the information on the safety, efficacy and proper use of Botox Vista® Injection 50 Units (hereinafter referred to as “Botox”) in adult patients less than 65 years, who undergo the treatment of expression lines of lateral canthus (crow’s feet lines) during actual use. Inclusion Criteria1) Patients who undergo the treatment with Botox for the first time (initial administration group) or2) Patients with an experience of the treatment with Botox (repeated administration group)3) Less than 65 years at the time of treatmentSample Size1080 patientsFollow-up PeriodAll patients shall be followed up from time of study drug injection to 6 months after study drug administration Total Survey Period2 years and 6 months after product launch Survey Items to be Collecteda) Information on Institutionb) Identifying Information on Patientc) Patient

Background Informationd) Prior Treatment History for Facial Wrinkles e) Information on Current Botox Administrationf) Information on Efficacy Evaluation (this includes evaluation of degree of winkle improvement by patient and physician, patient satisfaction with treatment)g) Use of Commitment Drug h) Information on Antibody Examination for Botulinum Toxin Type AI) Presence or Absence of AEsJ) Type of AEK) Evaluation of AE Relationship to Study DrugL) Exposure to Study Drug During Pregnancy

Study status
Ongoing

Research institution and networks

Institutions

Quintiles
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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
Planned:
14/06/2016

Study start date
Planned:
28/12/2016

Actual:
21/12/2016

Date of final study report
Planned:
22/08/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Allergan

Study protocol

(Japan) Botox in CFL E-DUI_protocol_20160316 (2).pdf(150.89 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 type list

Study type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness
Drug utilisation
Effectiveness study (incl. comparative)

Main study objective:
To collect and evaluate information on the safety, effectiveness and use of Botox Vista injection in adult patients younger than 65 years of age who are administered the study drug for the treatment of cross's feet lines.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine, other
Botox Vista Injection 50 units

Study drug International non-proprietary name (INN) or common name
BOTULINUM TOXIN TYPE A

Population studied

Age groups
Adults (18 to < 46 years)
Adults (46 to < 65 years)

Estimated number of subjects
1080

Study design details

Data analysis plan
Purely descriptive analysis.

Data management

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