

OBSERVATIONAL POST-AUTHORISATION SAFETY STUDY OF VISTABEL® FOR THE TREATMENT OF CROW'S FEET LINES (CFL)

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Study

Ongoing

Administrative details

EU PAS number

EUPAS15726

Study ID

23614

DARWIN EU® study

No

Study countries

 Belgium

 France

 Germany

 Sweden

Study status

Ongoing

Research institutions and networks

Institutions

Anita Verga

Contact details

Study institution contact

Anita Verga CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Anita Verga

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 07/09/2016

Study start date

Planned: 26/01/2017

Actual: 29/12/2016

Date of final study report

Planned: 24/08/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Allergan

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

191622-146

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To collect and assess the long-term safety profile of VISTABEL for treatment of CFL

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective, observational, multicenter study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(M03AX01) botulinum toxin

botulinum toxin

Medical condition to be studied

Skin wrinkling

Population studied

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

580

Study design details

Data analysis plan

Analyses will be performed on de-identified data. Analyses will be descriptive in nature, there are no plans for statistical testing or formal comparisons between groups. Results will be displayed in tabular format (i.e. summary statistics, frequency distribution of item responses, and incidence rates). No imputations for missing data are planned. All statistical analyses will be performed using SAS Version 9.2 or later.

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