Non-Interventional Post-Authorisation Safety Study of NUCEIVA for the Treatment of Moderate-to-Severe Glabellar Lines (EV-010)

First published: 29/07/2022

Last updated: 13/05/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS48390

Study ID

49251

DARWIN EU® study

No

Study countries

France

Germany

Spain

Sweden

United Kingdom

Study description

This is a prospective, multicentre, NI observational PASS, the 3 cohorts of interest include the total Safety Population, and the 2 sub-populations of botulinum toxin naïve and non-naïve patients. The purpose of this NI PASS is to add to the body of safety data collected in the clinical trial programme by further quantifying safety concerns and providing additional characterisation of the long-term safety of NUCEIVA that is reflective of real-world clinical practice. Safety data will be collected from approximately 750 patients at 20 sites throughout the UK and EU over an 18 month evaluation period.

Study status

Ongoing

Research institutions and networks

Institutions

Evolus Pharma

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Rose Monroe

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/11/2019

Study start date

Planned: 10/01/2023

Actual: 15/03/2023

Date of interim report, if expected

Planned: 10/02/2023

Actual: 13/06/2024

Date of final study report

Planned: 10/02/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Evolus Inc.

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

NCT05481931

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Other

Study topic, other:

Long-term safety as observed in real-world clinical practice of injectable for treatment of glabellar lines

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Study design:

750 patients will receive an initial 20U treatment. No additional treatments are required; patients may receive up to 6 treatments over 18 months. Patients will keep a diary of symptoms, side effects or health changes between visits. At the end of 18 months, staff will make final follow up call.

Main study objective:

Investigate the long-term safety of NUCEIVA as observed in the real-world clinical practice setting when administered as indicated in the EU/UK for the treatment of glabellar lines over an 18 month observation period.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

NI Observational PASS

Study drug and medical condition

Medicinal product name

NUCEIVA

Study drug International non-proprietary name (INN) or common name

BOTULINUM TOXIN TYPE A

Anatomical Therapeutic Chemical (ATC) code

(M03AX01) botulinum toxin

botulinum toxin

Medical condition to be studied

Skin wrinkling

Population studied

Short description of the study population

Male and female patients below the age of 65 years of age

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Estimated number of subjects

750

Study design details

Outcomes

To provide additional characterisation of the long-term safety of NUCEIVA while ensuring the systematic recording of previous exposure to botulinum toxin A. To collect and assess data on adverse events of particular interest defined as: eye disorders (including eyelid ptosis, brow ptosis, blepharospasm, muscle twitching, blurred vision, diplopia and muscle wasting), and, adverse events potentially suggestive of the distant spread of toxin (including dysphagia and dysphonia).

Data analysis plan

The Safety Population will consist of all patients who receive at least one treatment of NUCEIVA. All analyses will be performed on this safety population unless otherwise presented. Continuous data will be described using descriptive statistics: n, mean, standard deviation, median, minimum and maximum. Categorical data will be summarized as the number and percentage of patients in each category. Epidemiological methods will be used for the analysis of collected data. Analyses will be performed on de-identified data, and 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, and incidence rates. No imputations of missing data are planned. All statistical analyses will be performed using SAS Version 9.4 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