Effectiveness and Safety of SMART BoNT-A therapy with Dysport® in patients with post-stroke chronic upper limb spasticity in real-life setting (SMART-NIS)

First published: 03/01/2024

Last updated: 10/01/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/107723

EU PAS number

EUPAS107722

Study ID

107723

DARWIN EU® study

No

Study countries

Germany

Study description

The purpose of this study is to collect data for Dysport® SMART BoNT-A therapy usage in an office-based setting in post-stroke participants with chronic (> 6 months) focal Upper Limb Spasticity who have been under stable oral antispastics treatment or patients with no current anti-spasticity treatment.

Study status

Ongoing

Research institutions and networks

Institutions

Ipsen Pharma

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Director Medical

Study contact

clinical.trials@ipsen.com

Primary lead investigator

Director Medical

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 28/10/2021

Study start date

Actual: 05/05/2022

Data analysis start date

Planned: 31/05/2025

Date of final study report

Planned: 31/12/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Ipsen Pharma

Study protocol

CLIN-52120-456_protocol_V2.0_07Jul2023_Redacted_PDFA.pdf(9.2 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

NCT05224349

Link to ClinicalTrials.gov

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Main study objective:

To assess the effectiveness of AboBoNT-A SMART injections as Disability Assessment Scale (DAS) score on the Principal Target of Treatment (PTT) for the upper limb.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

SMART AbobotulinumtoxinA (AboBoNT-A; Dysport®)

Additional medical condition(s)

Post-stroke chronic upper limb spasticity

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

116

Study design details

Outcomes

- Change from baseline of Disability Assessment Scale (DAS) score in Principle Target of Treatment (PTT) for the upper limb.
- Change from baseline of Modified Ashworth Scale (MAS) Primary Target Muscle Group (PTMG).
- Change from baseline of pain assessed with Visual Analogue Scale (VAS).
- Change from baseline of Spasticity Related Quality of Life Tool (SQoL-6D).
- Incidence of Adverse Events (AEs).
- Incidence of Special Situations (SS).

Data analysis plan

All effectiveness analysis will be based on the Full Analysis Set population. Safety analysis will be performed on the safety population.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

- Patient medical file: The investigator or authorized medical staff will record clinical and treatment data (if applicable) from patients' medical files into the electronic Case Report Form (eCRF).
- Investigator scales: All data regarding the scales (DAS, MAS, Assessment of Pain (VAS)) used by the investigator during the study should be recorded from paper form into the eCRF or directly into the eCRF.
- QoL questionnaire: SQoL-6D data will be collected on a paper questionnaire completed by the participant at visit 1, 2, 3 and 4 and captured in eCRF by investigator.
- Questionnaire on patient-perceived satisfaction/ intention to continue / discontinue treatment and reasons for discontinuation, if applicable: data will be collected on a paper questionnaire completed by the participant at visit 3 and 4 and captured in eCRF by investigator.

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