Post marketing surveillance (non-interventional study) for evaluating the efficacy and safety of Dysport Czech patients suffering from post-stroke arm spasticity

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Last updated: 01/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS27784

Study ID

27785

DARWIN EU® study

No

Study countries

Czechia

Study description

To provide additional risk / benefit information on the use of Dysport within the approved indications. The Study is therefore non-interventional and is designed only to collect data that would normally be available in the standard treatment of patients with Dysport within licensed indication. As such, no additional measures of efficacy or safety are being collected other than those recorded in normal practice.

Study status

Finalised

Research institutions and networks

Institutions

Ipsen Pharma

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Institution

Multiple centres: 9 centres are involved in the study

Contact details

Study institution contact

Ipsen Medical Director clinical.trials@ipsen.com

Study contact

clinical.trials@ipsen.com

Primary lead investigator

Ipsen Medical Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/02/2008

Actual: 12/02/2008

Study start date

Planned: 12/11/2008

Actual: 12/11/2008

Data analysis start date

Planned: 13/04/2012

Actual: 13/04/2012

Date of final study report

Planned: 30/04/2015

Actual: 13/07/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Ipsen

Study protocol

A-38-52120-113_protocol-13Feb2012_Redacted.pdf (385.61 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

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

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To provide a further assessment of the risk / benefit of Dysport as a marketed product.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Open, non-randomised, multi-centre, non-interventional, post-marketing study

Study drug and medical condition

Medicinal product name, other

Dysport

Anatomical Therapeutic Chemical (ATC) code

(M03AX01) botulinum toxin

botulinum toxin

Medical condition to be studied

Muscle spasticity

Population studied

Short description of the study population

Adult subjects with Post-Stroke Arm Spasticity newly scheduled to receive Dysport, with stroke onset at least 3 months prior to study entry, within each participating centre are to be included in this Study. All subjects should rehabilitate under professional inspection at the same time.

Study Inclusion Criteria

All subjects must fulfil the following:

1. Subjects with stroke either haemorrhagical or ischemic origin and stroke onset at least 3 months prior to study entry scheduled to receive Dysport.
2. Adults over the age of 18 years
3. Arm spasticity with Modified Ashworth scale 2 at least in one part

Study Exclusion Criteria

Subjects presenting with any of the following will not be included in the Study:

1. Hypersensitivity to any Dysport ingredient
2. Pregnancy
3. Previous administration of botulinum toxin

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

48

Study design details

Outcomes

Global assessment of spasticity using the Modified Ashworth Scale, Patient´s Quality of Life (QOL) evaluation (DAS scale), Interval between separate administration sessions and monitoring of treatment related adverse events (RAEs).

Data analysis plan

The statistical analysis will be only descriptive: data summaries will consist of summary statistics like counts, mean, standard deviations, medians, minima, maxima or frequencies / percentages as appropriate. ITT / safety population will be used to describe all efficacy data and safety data. e.g. risk estimation, measures of risk, internal/external validity

Documents

Study results

A-38-52120-113_synopsis_no marks.pdf (2.27 MB)

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