A post marketing surveillance survey of Dysport for evaluating safety of Dysport in Korean patients suffering from Spasticity or Dystonia

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/35504

EU PAS number

EUPAS35503

Study ID

35504

DARWIN EU® study

No

Study countries

☐ Korea, Democratic People's Republic of

Study description

This is an open, non-randomised, multi-centre, non-interventional, post-marketing survey to collect safety data based on routine treatment of subjects with spasticity or dystonia.

Study status

Finalised

Research institutions and networks

Institutions

Ipsen Pharma

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Institution

Multiple centres: 13 centres are involved in the study

Contact details

Study institution contact

Medical Director

Study contact

clinical.trials@ipsen.com

Primary lead investigator

Medical Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 02/08/2006

Study start date

Planned: 08/01/2006

Actual: 08/02/2006

Data analysis start date

Planned: 31/01/2007

Actual: 15/03/2007

Date of final study report

Planned: 31/12/2015

Actual: 20/01/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Ipsen

Study protocol

a3852120114-protocol.pdf(4.27 MB)

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

Data collection methods:

Primary data collection

Main study objective:

To provide a further assessment of the benefit/risk effect of Dysport as a marketed product in Korean subjects suffering from spasticity or dystonia.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

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

Study drug and medical condition

Name of medicine, other

Dysport (UK)

Anatomical Therapeutic Chemical (ATC) code

(M03AX01) botulinum toxin

botulinum toxin

Medical condition to be studied

Cerebral palsy

Additional medical condition(s)

Equinus SpasticityCervical DystoniaHemifacial spasmSpasticity

Population studied

Short description of the study population

Each Investigator will maintain a record of all subjects enrolled into the survey. It is planned to recruit approximately 500 subjects in approximately 20 centres in Korea.

All subjects must fulfil the following:

1) Subjects with indication disease scheduled to receive Dysport as per normal treatment practice, and in respect with Dysport SmPC.

2) Adult or child over the age of 2 years

Subjects will not be included in the survey if :

1) Subject has hypersensitivity to Dysport or drugs with a similar chemical structure.

2) Treatment with any other investigational drug within the last 30 days before survey entry.

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

481

Study design details

Outcomes

Safety endpoint was the AEs, more specifically the number of AEs and the percentage of subjects with any AE.

Data analysis plan

The sample size of 500 is based on feasibility and not on any statistical considerations. In terms of study reporting, the analysis is descriptive: data summaries consist of descriptive statistics like counts, means, standard deviations, medians, minima, maxima or frequencies / percentages as appropriate. The safety analysis is based on the safety population (defined as all treated patients).

Documents

Study results

a3852120114-synopsis.pdf(2.98 MB)

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