



Clinical trial results:

A Phase III, Multicenter, Double Blind, Randomised, Placebo Controlled Study to Assess the Efficacy and the Safety of a Single Cycle of Dysport Solution in the Treatment of Upper Limb Spasticity in Adult Subjects with Spastic Hemiparesis due to Stroke

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2015-000554-38 |
| Trial protocol | BE CZ SK IT |
| Global end of trial date | 16 June 2017 |

Results information

| | |
|-----------------------------------|---|
| Result version number | v1 (current) |
| This version publication date | 24 July 2020 |
| First version publication date | 24 July 2020 |
| Summary attachment (see zip file) | Notice of Study Withdrawal (Notice of Study Withdrawal_2015-000554-38.docx) |

Trial information

Trial identification

| | |
|-----------------------|----------------|
| Sponsor protocol code | D-FR-52120-221 |
|-----------------------|----------------|

Additional study identifiers

| | |
|------------------------------------|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | - |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Ipsen |
| Sponsor organisation address | 5 Avenue du Canada, Les Ulis, France, 91940 |
| Public contact | Medical Director, Ipsen Innovation, clinical.trials@ipsen.com |
| Scientific contact | Medical Director, Ipsen Innovation, clinical.trials@ipsen.com |

Notes:

Paediatric regulatory details

| | |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|--|--------------|
| Analysis stage | Final |
| Date of interim/final analysis | 16 June 2017 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 16 June 2017 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of Dysport Solution 1000 Units (U) compared to placebo in reducing the upper limb muscle tone (using the Modified Ashworth Scale [MAS]) in adult subjects with upper limb spastic hemiparesis due to stroke after one treatment cycle.

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 16 June 2017 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects**Subjects enrolled per country**

| | |
|--------------------------------------|-----------------------|
| Country: Number of subjects enrolled | Czech Republic: 99999 |
| Worldwide total number of subjects | 99999 |
| EEA total number of subjects | 99999 |

Notes:

Subjects enrolled per age group

| | |
|---|-------|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 99999 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

99999 is "not applicable" value or 0 participants. This trial was cancelled with no participants enrolled.

Pre-assignment

Screening details:

Not applicable

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall Trial (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|--|------------------------|
| Arm title | Dysport |
| Arm description: | |
| Dysport Solution 1000 U | |
| Arm type | Experimental |
| Investigational medicinal product name | Dysport |
| Investigational medicinal product code | |
| Other name | AbobotulinumtoxinA |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Dose would have been 1000 U by intramuscular injection on Day 1.

| | |
|---------------------------------------|---------|
| Number of subjects in period 1 | Dysport |
| Started | 99999 |
| Completed | 99999 |

Baseline characteristics

Reporting groups

Reporting group title

Overall Trial

Reporting group description:

99999 is "not applicable" value or 0 participants. This trial was cancelled with no participants enrolled.

| Reporting group values | Overall Trial | Total | |
|---|---------------|-------|--|
| Number of subjects | 99999 | 99999 | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 0 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 99999 | 99999 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 99999 | 99999 | |
| Male | 0 | 0 | |

End points

End points reporting groups

| | |
|---|---------|
| Reporting group title | Dysport |
| Reporting group description: Dysport Solution 1000 U | |

Primary: Proportion of Subjects by MAS Category in the Primary Targeted Muscle Group at Week 4

| | |
|--|--|
| End point title | Proportion of Subjects by MAS Category in the Primary Targeted Muscle Group at Week 4 ^[1] |
| End point description: 99999 is "not applicable" value or 0 participants. This trial was cancelled with no participants enrolled. | |
| End point type | Primary |
| End point timeframe: Not applicable | |

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No participants were enrolled in the trial hence results are not available.

| End point values | Dysport | | | |
|-----------------------------|----------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 99999 ^[2] | | | |
| Units: not applicable | | | | |
| number (not applicable) | 99999 | | | |

Notes:

[2] - No participants were enrolled in the trial hence results are not available.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

All adverse events occurring during the course of the clinical trial were to be collected.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|---|
| Dictionary version | 0 |
|--------------------|---|

Reporting groups

| | |
|-----------------------|---------|
| Reporting group title | Dysport |
|-----------------------|---------|

Reporting group description:

Dysport Solution 1000 U

| Serious adverse events | Dysport | | |
|---|-------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 99999 (0.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |

Frequency threshold for reporting non-serious adverse events: 0 %

| Non-serious adverse events | Dysport | | |
|---|-------------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 99999 (0.00%) | | |

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: No participants were enrolled in the trial hence results are not available.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

| |
|--|
| 99999 is "not applicable" value or 0 participants. The sponsor made the decision to cancel the trial before it was started. Zero participants were enrolled. |
|--|

Notes: