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: