Clinical trial results:
ACTION OF THE AMANTADINE ON POST STROKE APHASIC PATIENTS LANGUAGE AND COMMUNICATION

Summary

EudraCT number	2008-003945-10
Trial protocol	FR
Global end of trial date	04 April 2014

Results information

Result version number	v1 (current)
This version publication date	29 June 2022
First version publication date	29 June 2022
Summary attachment (see zip file)	end study (End Study.pdf)

Trial information

Trial identification

Sponsor protocol code	01-APN-08

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	chu de nice
Sponsor organisation address	DRCI-Hôpital de Cimiez - 4 avenue reine victoria, Nice, France, 06003
Public contact	Directeur de la DRCI, CHU de Nice - DRCI, +33 492034589, caillon.c@chu-nice.fr
Scientific contact	Investigateur Principal, CHU de Nice - Pr Chatel, 0033 492034011, caillon.c@chu-nice.fr

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	04 April 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 April 2014
Global end of trial reached?	Yes
Global end of trial date	04 April 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To confirm by a «drug test", using amantadine as dopamine agonist, the possibility of significantly improving the verbal fluency and communication of patients with "not fluent" aphasia at the chronic stage when logopedic rehabilitation is "stabilized" (> 6months).

Protection of trial subjects:

Patients had an expressive aphasia caused by a cerebrovascular accident.
The stroke had to have occurred at least six months previously, with no historical limit. Patients with many years of aphasia were equally eligible. All patients had undergone investigations to establish the extent of the stroke, any underlying risk factors at the time of the stroke, and had had rehabilitation that included speech therapy subsequently. Their recovery was considered stable with no progression.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 November 2009
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	France: 50
Worldwide total number of subjects	50
EEA total number of subjects	50

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)	50
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Inclusion period

Period 1

Period 1 title	Inclusion period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	0Amantadine

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Amantadine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Orodispersible tablet
Routes of administration	Buccal use

Dosage and administration details:

3 days Amantadine, 4 days de wash out and 3 days Placebo

Number of subjects in period 1	0Amantadine
Started	50
Completed	50

Baseline characteristics

End points

End points reporting groups

Reporting group title	0Amantadine
Reporting group description: -	
Subject analysis set title	50
Subject analysis set type	Intention-to-treat

Subject analysis set description:

An intention-to-treat analysis was performed (each patient having taken at least one treatment dose), using an analysis of variance, after verification of the absence of carry-over effect, taking into account the sequence effect (the order of administration of treatment) and the period effect.

Primary: the verbal fluency

End point title	the verbal fluency[1]

End point description:

Fluency was studied according to its two components, lexical and semantic.

End point type	Primary

End point timeframe:

2 years

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: The statistical analysis of the main criterion is described in the attached document

End point values	0Amantadine			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: Number	50			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Thirteen secondary effects were observed, 11 during placebo treatment of which 2 [diarrhea and malaise] were recorded as severe and led to the withdrawal of these patients from the study, and 2 during amantadine treatment

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19

Frequency threshold for reporting non-serious adverse events: 1 %

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: The 2 adverse events are diarrhea and are not considered serious. Treatment has been stopped.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 June 2009	add test on visit
05 November 2010	Prolongation study

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported