Clinical trial results:
Rotterdam Observational Study in CIDP of Pharmacokinetics of Intravenous -globulin

Summary

EudraCT number	2013-004988-32
Trial protocol	NL
Global end of trial date	25 October 2015

Results information

Result version number	v1 (current)
This version publication date	13 December 2021
First version publication date	13 December 2021
Summary attachment (see zip file)	PKPD_IVIg_CIDP (Fokkink_et_al-2017-Clinical_Pharmacology_&_Therapeutics_final.pdf)

Trial information

Trial identification

Sponsor protocol code	NL46993.078.13

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Erasmus MC
Sponsor organisation address	Dr. Molewaterplein 50, Rotterdam, Netherlands, PO 2040 3000CA
Public contact	GBS workgroup Erasmus MC, Erasmus University Medical Center, 0031 0107043430,
Scientific contact	GBS workgroup Erasmus MC, Erasmus University Medical Center, 0031 0107043430,

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	30 November 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 October 2015
Global end of trial reached?	Yes
Global end of trial date	25 October 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study is to determine the PK and PD of IVIg during maintenance treatment in patients with CIDP. These data will be used to conduct a NONMEM analysis in relation to the dosage, frequency and batch of IVIg used.

Protection of trial subjects:

The canula for IV administration was left in place longer to obtain serum samples shortly after infusion in order to minimize blood drawings.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 April 2014
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	Netherlands: 15
Worldwide total number of subjects	15
EEA total number of subjects	15

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)	5
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Screening criteria were: must be diagnosed with CIDP (EFNS/PNS), EMG findings compatible with this diagnosis, age 18 and older, be on maintenance treatment with IVIg, agree on and sign the informed consent.

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	Overall trial
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Kiovig
Investigational medicinal product code	J06BA02
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Highly variable and patient dependent: ranges from 15 to 60 (g). g gram(s)

Number of subjects in period 1	Overall trial
Started	15
Completed	15

Baseline characteristics

Reporting groups

Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	15	15	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
median	69		
full range (min-max)	37 to 79	-	
Gender categorical Units: Subjects			
Female	4	4	
Male	11	11	

End points

End points reporting groups

Reporting group title	Overall trial

Reporting group description: -

Primary: Serum IgG levels

End point title	Serum IgG levels[1]

End point description:

End point type	Primary

End point timeframe:

From first sample collected (30-04-214) until last sample collected (25-10-2015)

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: Primary and secondary pharmacokinetic parameters were calculated using PKSolver's version 2.0 noncompartmental analysis tool for infusion (Linear
up – Log down) or the two-compartmental option. There are no arms to compare, yet adding a statistical analysis with one arm keeps getting flagged as an error (despite the option is given). Hence to complete this form no statistical analyses were specified. For an overwie of statistical analyses used please see the linked and/or enclosed publication.

End point values	Overall trial			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: g/L				
number (not applicable)	15			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

From start of the trial (30-04-2014) until the last blood sample was collected (25-10-2015).

Assessment type	Systematic

Dictionary used

Dictionary name	Excel
Dictionary version	2010

Reporting groups

Reporting group title	All subjects

Reporting group description: -

Serious adverse events	All subjects		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (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	All subjects		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 15 (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: SAEs during or after treatment with IVIg in general are rare, given all these patients were on maintenance treatment with IVIg before inclusion in the trial the ocurrence of any AE was a priori very limited. After completion of the last blood sample collection no AE was objectified and/or reported.

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

None reported