Clinical trial results:
Peripheral neuropathy as potential side effect in patients with multiple sclerosis treated with teriflunomide.

Summary

EudraCT number	2021-002810-15
Trial protocol	BE
Global end of trial date	20 January 2022

Results information

Result version number	v1 (current)
This version publication date	25 April 2022
First version publication date	25 April 2022

Trial information

Trial identification

Sponsor protocol code	CHUB-Neuro-ENMG-MS

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	CHU Brugmann
Sponsor organisation address	4 Place A. Van Gehuchten , Brussels, Belgium, 1020
Public contact	Neurology Department, CHU Brugmann, 32 24772446, Bernard.DACHY@chu-brugmann.be
Scientific contact	Neurology Department, CHU Brugmann, 32 24772446, Bernard.DACHY@chu-brugmann.be

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 March 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 January 2022
Global end of trial reached?	Yes
Global end of trial date	20 January 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To explore the incidence of peripheral nerve abnormalities, investigated by Nerve Conduction Study, in patients with multiple sclerosis treated with teriflunomide.

Protection of trial subjects:

Aubagio (teriflunomide) is used as standard of care medication in the CHU Brugmann Hospital for patients with a diagnosis of multiple sclerosis (MS).
Nerve conduction studies are routinely performed in the Neurology Departement and do not put the patients at risk.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 July 2021
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	Belgium: 12
Worldwide total number of subjects	12
EEA total number of subjects	12

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)	11
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were included in the CHU Brugmann Hospital (Brussels, Belgium) only. Patients with previous diagnosis of multiple sclerosis and currently treated with teriflunomide as standard of care were retrospectively identified and prospectively screened for peripheral nerve abnormalities by Nerve Conduction Studies.

Pre-assignment

Screening details:

20 patients were identified in specialized consultations in multiple sclerosis of CHU Brugmann Hospital. 12 patients signed the informed consent. They all completed all the examinations of the Nerve Conduction Stimulation Testing.

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	Teriflunomide

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Teriflunomide
Investigational medicinal product code	
Other name	Aubagio 14 mg
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

Aubagio 14mg (coated tablet) once per day, oral use

Number of subjects in period 1	Teriflunomide
Started	12
Completed	12

Baseline characteristics

Reporting groups	
Reporting group title	Overall Trial

Reporting group description: -

Reporting group values	Overall Trial	Total	
Number of subjects	12	12	
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)	11	11	
From 65-84 years	1	1	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	4	4	
Male	8	8	

End points

End points reporting groups

Reporting group title	Teriflunomide

Reporting group description: -

Primary: Mean DL, right median nerve, motor response

End point title	Mean DL, right median nerve, motor response[1]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	3.0 (2.5 to 3.85)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean distal amplitude , right median nerve, motor response

End point title	Mean distal amplitude , right median nerve, motor response[2]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[2] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mV				
arithmetic mean (full range (min-max))	8.3 (3.1 to 13.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean proximal amplitude, right median nerve, motor response

End point title	Mean proximal amplitude, right median nerve, motor

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[3] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mV				
arithmetic mean (full range (min-max))	7.8 (2.9 to 12.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean NCV, right median nerve, motor response

End point title	Mean NCV, right median nerve, motor response[4]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[4] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is

only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: m/s				
arithmetic mean (full range (min-max))	59 (52 to 64)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean F-wave latency, right median nerve, motor response

End point title	Mean F-wave latency, right median nerve, motor response[5]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[5] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	27 (23 to 29)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL, left median nerve, motor response

End point title	Mean DL, left median nerve, motor response[6]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[6] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	3.2 (2.7 to 3.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean distal amplitude, left median nerve, motor response

End point title	Mean distal amplitude, left median nerve, motor response[7]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[7] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mV				
arithmetic mean (full range (min-max))	7.1 (3.4 to 11.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean proximal amplitude, left median nerve, motor response

End point title	Mean proximal amplitude, left median nerve, motor response[8]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an

appointment for this examination.

Notes:

[8] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mV				
arithmetic mean (full range (min-max))	6.6 (2.8 to 11.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean NCV, left median nerve, motor response

End point title	Mean NCV, left median nerve, motor response[9]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[9] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: m/s				
arithmetic mean (full range (min-max))	58 (53 to 67)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean F-wave latency, left median nerve, motor response

End point title	Mean F-wave latency, left median nerve, motor response[10]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[10] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	26 (22 to 29)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL, right ulnar nerve, motor response

End point title	Mean DL, right ulnar nerve, motor response[11]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[11] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	2.3 (1.7 to 2.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean distal amplitude, right ulnar nerve, motor response

End point title	Mean distal amplitude, right ulnar nerve, motor response[12]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[12] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mV				
arithmetic mean (full range (min-max))	8.2 (5.7 to 12.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean proximal amplitude, right ulnar nerve, motor response

End point title	Mean proximal amplitude, right ulnar nerve, motor response[13]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[13] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mV				
arithmetic mean (full range (min-max))	7.4 (4.8 to 9.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean NCV, right ulnar nerve, motor response

End point title	Mean NCV, right ulnar nerve, motor response[14]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[14] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: m/s				
arithmetic mean (full range (min-max))	62 (53 to 74)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean F-wave latency, right ulnar nerve, motor response

End point title	Mean F-wave latency, right ulnar nerve, motor response[15]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[15] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	28 (23 to 30)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL, left ulnar nerve, motor nerve

End point title	Mean DL, left ulnar nerve, motor nerve[16]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[16] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	2.4 (2.0 to 2.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean distal amplitude, left ulnar nerve, motor response

End point title	Mean distal amplitude, left ulnar nerve, motor response[17]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[17] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mV				
arithmetic mean (full range (min-max))	8.8 (5.7 to 12.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean proximal amplitude, left ulnar nerve, motor response

End point title	Mean proximal amplitude, left ulnar nerve, motor response[18]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[18] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mV				
arithmetic mean (full range (min-max))	8.3 (4.6 to 11.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean NCV, left ulnar nerve, motor response

End point title	Mean NCV, left ulnar nerve, motor response[19]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[19] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: m/s				
arithmetic mean (full range (min-max))	59 (54 to 66)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean F-wave latency, left ulnar nerve, motor response

End point title	Mean F-wave latency, left ulnar nerve, motor response[20]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[20] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	27 (23 to 30)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL, right peroneal nerve, motor response

End point title	Mean DL, right peroneal nerve, motor response[21]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[21] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	3.9 (2.8 to 6.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean distal amplitude, right peroneal nerve, motor response

End point title	Mean distal amplitude, right peroneal nerve, motor response[22]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[22] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mV				
arithmetic mean (full range (min-max))	6.9 (1.9 to 10.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean proximal amplitude, right peroneal nerve, motor response

End point title	Mean proximal amplitude, right peroneal nerve, motor response[23]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[23] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mV				
arithmetic mean (full range (min-max))	6.4 (1.7 to 10.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean NCV, right peroneal nerve, motor response

End point title	Mean NCV, right peroneal nerve, motor response[24]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[24] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: m/s				
arithmetic mean (full range (min-max))	48 (40 to 56)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean F-wave latency, right peroneal nerve, motor response

End point title	Mean F-wave latency, right peroneal nerve, motor response[25]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[25] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	49 (42 to 62)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL, Left peroneal nerve, motor response

End point title	Mean DL, Left peroneal nerve, motor response[26]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[26] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	4.0 (3.1 to 5.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean distal amplitude, left peroneal nerve, motor response

End point title	Mean distal amplitude, left peroneal nerve, motor response[27]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[27] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mV				
arithmetic mean (full range (min-max))	5.9 (3.8 to 10)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean proximal amplitude, left peroneal nerve, motor response

End point title	Mean proximal amplitude, left peroneal nerve, motor

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[28] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mV				
arithmetic mean (full range (min-max))	5.5 (3.1 to 9.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean NCV, left peroneal nerve, motor response

End point title	Mean NCV, left peroneal nerve, motor response[29]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[29] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: m/s				
arithmetic mean (full range (min-max))	47 (43 to 51)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean F-wave latency, left peroneal nerve, motor response

End point title	Mean F-wave latency, left peroneal nerve, motor response[30]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[30] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	50 (42 to 59)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL, right tibial nerve, motor response

End point title	Mean DL, right tibial nerve, motor response[31]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[31] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	4.2 (3.1 to 5)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean distal amplitude, right tibial nerve, motor response

End point title	Mean distal amplitude, right tibial nerve, motor response[32]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[32] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mV				
arithmetic mean (full range (min-max))	11.9 (5.9 to 16.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean proximal amplitude, right tibial nerve, motor response

End point title	Mean proximal amplitude, right tibial nerve, motor response[33]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[33] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mV				
arithmetic mean (full range (min-max))	9.3 (4.7 to 13.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean NCV, right tibial nerve, motor response

End point title	Mean NCV, right tibial nerve, motor response[34]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[34] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: m/s				
arithmetic mean (full range (min-max))	46 (40 to 53)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean F-wave latency, right tibial nerve, motor response

End point title	Mean F-wave latency, right tibial nerve, motor response[35]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[35] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	51 (42 to 59)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL, left tibial nerve, motor response

End point title	Mean DL, left tibial nerve, motor response[36]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[36] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	4.4 (3.3 to 6.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean distal amplitude, left tibial nerve, motor response

End point title	Mean distal amplitude, left tibial nerve, motor response[37]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[37] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mV				
arithmetic mean (full range (min-max))	12.5 (5.6 to 23.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean NCV, left tibial nerve, motor response

End point title	Mean NCV, left tibial nerve, motor response[38]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[38] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: m/s				
arithmetic mean (full range (min-max))	46 (41 to 54)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean F-wave latency, left tibial nerve, motor response

End point title	Mean F-wave latency, left tibial nerve, motor response[39]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[39] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	51 (45 to 59)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL onset, right median nerve, sensory response

End point title	Mean DL onset, right median nerve, sensory response[40]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[40] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	2.8 (2.3 to 3.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL Peak, right median nerve, sensory response

End point title	Mean DL Peak, right median nerve, sensory response[41]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[41] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	3.6 (3.1 to 4.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean amplitude, right median nerve, sensory response

End point title	Mean amplitude, right median nerve, sensory response[42]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[42] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: µV				
arithmetic mean (full range (min-max))	29.6 (19.2 to 59.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean NCV, right median nerve, sensory response

End point title	Mean NCV, right median nerve, sensory response[43]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[43] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: m/s				
arithmetic mean (full range (min-max))	52 (46 to 59)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL onset, left median nerve, sensory response

End point title	Mean DL onset, left median nerve, sensory response[44]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[44] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	2.9 (2.5 to 3.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL peak, left median nerve, sensory response

End point title	Mean DL peak, left median nerve, sensory response[45]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[45] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	3.7 (3.3 to 4.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean amplitude, left median nerve, sensory response

End point title	Mean amplitude, left median nerve, sensory response[46]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[46] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: µV				
arithmetic mean (full range (min-max))	29.3 (19.6 to 64.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean NCV, left median nerve, sensory response

End point title	Mean NCV, left median nerve, sensory response[47]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[47] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: m/s				
arithmetic mean (full range (min-max))	51 (46 to 63)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL onset, right ulnar nerve, sensory response

End point title	Mean DL onset, right ulnar nerve, sensory response[48]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[48] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	2.5 (1.9 to 2.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL peak, right ulnar nerve, sensory response

End point title	Mean DL peak, right ulnar nerve, sensory response[49]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[49] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	3.3 (2.5 to 4.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean amplitude, right ulnar nerve, sensory response

End point title	Mean amplitude, right ulnar nerve, sensory response[50]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[50] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: µV				
arithmetic mean (full range (min-max))	28.7 (18.0 to 52.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean NCV, right ulnar nerve, sensory response

End point title	Mean NCV, right ulnar nerve, sensory response[51]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[51] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: m/s				
arithmetic mean (full range (min-max))	50 (45 to 59)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL onset, left ulnar nerve, sensory response

End point title	Mean DL onset, left ulnar nerve, sensory response[52]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[52] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	2.5 (2.0 to 2.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL peak, left ulnar nerve, sensory response

End point title	Mean DL peak, left ulnar nerve, sensory response[53]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[53] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	3.3 (2.7 to 3.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean amplitude, left ulnar nerve, sensory response

End point title	Mean amplitude, left ulnar nerve, sensory response[54]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[54] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: µV				
arithmetic mean (full range (min-max))	27.7 (13.5 to 52.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean NCV, left ulnar nerve, sensory response

End point title	Mean NCV, left ulnar nerve, sensory response[55]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[55] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: m/s				
arithmetic mean (full range (min-max))	50 (45 to 57)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL onset, right radial nerve, sensory response

End point title	Mean DL onset, right radial nerve, sensory response[56]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[56] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	2.0 (1.7 to 2.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL peak, right radial nerve, sensory response

End point title	Mean DL peak, right radial nerve, sensory response[57]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[57] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	2.7 (2.3 to 3.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean amplitude, right radial nerve, sensory response

End point title	Mean amplitude, right radial nerve, sensory response[58]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[58] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	23.4 (15.1 to 44.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean NCV, right radial nerve, sensory response

End point title	Mean NCV, right radial nerve, sensory response[59]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[59] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: m/s				
arithmetic mean (full range (min-max))	51 (45 to 60)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL onset, left radial nerve, sensory response

End point title	Mean DL onset, left radial nerve, sensory response[60]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[60] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	2.0 (1.7 to 2.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL peak, left radial nerve, sensory response

End point title	Mean DL peak, left radial nerve, sensory response[61]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[61] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	2.7 (2.3 to 3.1)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean amplitude, left radial nerve, sensory response

End point title	Mean amplitude, left radial nerve, sensory response[62]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[62] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: µV				
arithmetic mean (full range (min-max))	21.5 (15.5 to 30.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean NCV, left radial nerve, sensory response

End point title	Mean NCV, left radial nerve, sensory response[63]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[63] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: m/s				
arithmetic mean (full range (min-max))	51 (46 to 60)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL peak, right sural nerve, sensory response

End point title	Mean DL peak, right sural nerve, sensory response[64]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[64] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	4.4 (3.5 to 5.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean amplitude, right sural nerve, sensory response

End point title	Mean amplitude, right sural nerve, sensory response[65]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[65] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: µV				
arithmetic mean (full range (min-max))	11.3 (5.6 to 20.1)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean NCV, right sural nerve, sensory response

End point title	Mean NCV, right sural nerve, sensory response[66]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[66] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: µV				
arithmetic mean (full range (min-max))	43 (35 to 46)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL onset, left sural nerve, sensory response

End point title	Mean DL onset, left sural nerve, sensory response[67]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[67] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	3.3 (2.9 to 4.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL peak, left sural nerve, sensory response

End point title	Mean DL peak, left sural nerve, sensory response[68]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[68] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	4.4 (3.8 to 5.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean amplitude, left sural nerve, sensory response

End point title	Mean amplitude, left sural nerve, sensory response[69]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[69] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: µV				
arithmetic mean (full range (min-max))	9.9 (5.2 to 21.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean NCV, left sural nerve, sensory response

End point title	Mean NCV, left sural nerve, sensory response[70]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[70] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: m/s				
arithmetic mean (full range (min-max))	42 (35 to 48)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean proximal amplitude, left tibial nerve, motor response

End point title	Mean proximal amplitude, left tibial nerve, motor response[71]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[71] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mV				
arithmetic mean (full range (min-max))	10.2 (4.7 to 19.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean DL onset, right sural nerve, sensory response

End point title	Mean DL onset, right sural nerve, sensory response[72]

End point description:

End point type	Primary

End point timeframe:

Nerve conduction study performed only once, timepoint depending on the delays to obtain an appointment for this examination.

Notes:

[72] - 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: This is a monocentric, open-label, non-controlled, not randomized, phase IV study. There is only one study arm.

End point values	Teriflunomide			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ms				
arithmetic mean (full range (min-max))	3.3 (2.5 to 4.0)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: Entire trial	
Assessment type	Systematic

Dictionary used	
Dictionary name	Current nomenclature
Dictionary version	2022

Reporting groups	
Reporting group title	Teriflunomide

Reporting group description: -

Serious adverse events	Teriflunomide		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Teriflunomide		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 12 (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: There were no non-serious adverse events reported by the principal investigator. The IMP used in this trial (teriflunomide) has a marketing authorization and is indicated for patients with multiple sclerosis. Inclusion criteria restricted the trial population to patients already taking teriflunomide as standard of care medication for their multiple sclerosis. The trial interventions were limited to the screening (once only) for peripheral nerve abnormalities by Nerve Conduction Studies.

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