EU Clinical Trials Register

Clinical trial results:
A Prospective, Non-interventional, Multicenter, Open-label Safety and Efficacy Study of Intravenous Natalizumab Administered to Patients With Relapsing Forms of Multiple Sclerosis who Participated in STRATA

EudraCT number	2014-003669-97
Trial protocol	BE
Global end of trial date	12 January 2017

Result version number	v1 (current)
This version publication date	22 August 2019
First version publication date	22 August 2019

Sponsor protocol code	BEL-TYS-14-10675

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

Notes:

Sponsor organisation name	Biogen
Sponsor organisation address	250 Binney Street, Cambridge, United States, 02142
Public contact	Biogen Study Medical Director, Biogen, clinicaltrials@biogen.com
Scientific contact	Biogen Study Medical Director, Biogen, clinicaltrials@biogen.com

Notes:

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:

Analysis stage	Final
Date of interim/final analysis	12 January 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 January 2017
Was the trial ended prematurely?	No

Notes:

Main objective of the trial:

The primary objective for this study was long-term safety (incidence and pattern of serious adverse events) in subjects receiving natalizumab.

Protection of trial subjects:

Written informed consent was obtained from each subject prior to evaluations performed for eligibility. Subjects were given adequate time to review the information in the informed consent and were allowed to ask, and have answered, questions concerning all portions of the conduct of the study

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 December 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Country: Number of subjects enrolled	Belgium: 7
Worldwide total number of subjects	7
EEA total number of subjects	7

Notes:

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)	7
From 65 to 84 years	0
85 years and over	0

Recruitment details:

Subjects were recruited from 4 sites in Belgium.

Screening details:

A total of 7 subjects with relapsing forms of multiple sclerosis were enrolled in the study.

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

	Natalizumab 300 milligram (mg)

Arm description:

Subjects received single dose of natalizumab 300 mg infusion, intravenously, once every 4 weeks for 96 weeks.

Arm type	Experimental
Investigational medicinal product name	Natalizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Single dose of natalizumab 300 mg infusion, intravenously, once every 4 weeks for 96 weeks

	Natalizumab 300 milligram (mg)
Started	7
Completed	3
Not completed	4
Consent withdrawn by subject	1
Unknown	1
Subject moved to another center	1
Treatment Stopped	1

Reporting group title	Overall Period

Reporting group description:

Subjects received single dose of natalizumab 300 mg infusion, intravenously, once every 4 weeks for 96 weeks.

	Overall Period	Total	
Number of subjects	7	7	
Age Categorical Units: Subjects			
Age Continuous Units: years median full range (min-max)	 59 18 to 61	 -	
Gender Categorical Units: Subjects			
Female Male	6 1	6 1	

Reporting group title	Natalizumab 300 milligram (mg)

Reporting group description:

Subjects received single dose of natalizumab 300 mg infusion, intravenously, once every 4 weeks for 96 weeks.

End point title	Number of Subjects with Adverse Events (AEs) and Serious Adverse Events (SAEs)[1]

End point description:

An AE is any untoward medical occurrence in a subject or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An SAE is any untoward medical occurrence that at any dose results in death, places the subject at immediate risk of death, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, results in a congenital anomaly/birth defect, or is a medically important event. Safety analysis set included all subjects enrolled in the study.

End point type	Primary

End point timeframe:

up to 96 weeks

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: Only descriptive analysis was planned to be reported for this endpoint.

	Natalizumab 300 milligram (mg)			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: subjects				
AEs	5			
SAEs	1			

No statistical analyses for this end point

End point title	Expanded Disability Status Scale (EDSS) Score to Measure Disability Progression at Week 0, 24, 48, 72 and 96

End point description:

EDSS is used to measure disability progression. EDSS score ranges from 0.0 (normal neurological exam) to 10.0 (death due to multiple sclerosis {MS}). Disability progression is defined as 1.5-point increase from baseline in subjects with baseline EDSS score = 0.0; OR 1-point increase in EDSS from baseline in subjects with baseline EDSS score of 1.0 to 5.0 inclusive; OR 0.5-point increase in EDSS from baseline in subjects with baseline EDSS score >5.0. Higher scores indicates worsening of disability progression. Full analysis set (FAS) included all subjects enrolled in the study.

End point type	Secondary

End point timeframe:

Baseline, Week 24, 48, 72 and 96

	Natalizumab 300 milligram (mg)			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: score on a scale				
median (full range (min-max))				
Week 0	2.0 (2.0 to 2.5)			
Week 24	2.5 (2.0 to 2.5)			
Week 48	2.5 (2.0 to 2.5)			
Week 72	2.5 (2.0 to 2.5)			
Week 96	2.25 (2.0 to 2.5)			

No statistical analyses for this end point

End point title	Number of Subjects with Clinical Relapses

End point description:

Multiple Sclerosis (MS) disease activity was assessed by the occurrence of clinical relapses over the study period. FAS included all subjects enrolled in the study.

End point type	Secondary

End point timeframe:

up to week 96

	Natalizumab 300 milligram (mg)			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: subjects	0			

No statistical analyses for this end point

Week 96	50			

No statistical analyses for this end point

End point title	EuroQol-5D (EQ-5D) Score to Assess Quality of life (QoL) at Week 0, 24, 48, 72 and 96

End point description:

The health-related quality of life (HRQoL) was measured using the global evaluation scale of the EuroQol-5 Dimensions (EQ-5D) questionnaire every 6 months. Subjects were asked to evaluate their health status on a scale from 0 (worst possible health status) to 10 (best possible health status). Highest scores indicates healthy quality of life. A average score for all the subjects were reported. FAS included all subjects enrolled in the study.

End point type	Secondary

End point timeframe:

Baseline, Week 24, 48, 72 and 96

	Natalizumab 300 milligram (mg)			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: score on a scale				
median (full range (min-max))				
Week 0	7.00 (7.00 to 7.50)			
Week 24	7.00 (7.00 to 7.50)			
Week 48	7.50 (7.00 to 7.50)			
Week 72	7.50 (7.00 to 7.50)			
Week 96	7.00 (7.00 to 7.50)			

No statistical analyses for this end point

End point title	Cognitive Evaluation by Symbol Digit Modalities Test (SDMT) at Week 0, 24, 48, 72 and 96

End point description:

Data for this endpoint was not collected.

End point type	Secondary

End point timeframe:

Baseline, Week 24, 48, 72 and 96

	Natalizumab 300 milligram (mg)			
Subject group type	Reporting group			
Number of subjects analysed	0[2]			
Units: score on a scale				
arithmetic mean (standard deviation)	()			

Notes:

[2] - Data was not collected.

No statistical analyses for this end point

Timeframe for reporting adverse events:	
Up to 96 weeks	
Assessment type	Non-systematic

Dictionary name	PI observed events
Dictionary version	0.0

Reporting group title	Natalizumab 300 mg
Reporting group description:	
Subjects received single dose of natalizumab 300 mg infusion, intravenously, once every 4 weeks for 96 weeks.	

	Natalizumab 300 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 7 (14.29%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
General disorders and administration site conditions			
Fracture (right malleolar)			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

	Natalizumab 300 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 7 (71.43%)		
General disorders and administration site conditions			
Fracture (4th right finger)			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Common cold			

subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Diarrhea			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Abdominal cramps			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Urinary infection			
subjects affected / exposed	2 / 7 (28.57%)		
occurrences (all)	2		
Allergic reaction to spiruline			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Gastric reflux			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Throat infection			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Upper respiratory tract infection			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		

Were there any global substantial amendments to the protocol? No

Were there any global interruptions to the trial? No

None reported