Corticosteroids for Immune Reconstitution Inflammatory Syndrome (IRIS)

This study has been terminated.

(This study was stopped prematurely due to lack of enrollment within a 1-5-year period.)

Sponsor:
Biogen Idec

Collaborator:
Elan Pharmaceuticals

Information provided by (Responsible Party):
Biogen Idec

ClinicalTrials.gov Identifier:
NCT01211665

First received: July 29, 2010
Last updated: August 26, 2014
Last verified: August 2014
History of Changes

Results First Received: July 23, 2014

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Immune Reconstitution Inflammatory Syndrome Leukoencephalopathy, Progressive Multifocal
Interventions:	Drug: Methylprednisolone Drug: Prednisolone

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Pulsed IVMP	Intravenous methylprednisolone (IVMP) 1 g/day administered the first 3 days of each weekly cycle, and repeated for 3 additional cycles (totaling 4 cycles). If necessary, 2 additional weekly cycles of 1 g IVMP daily for 3 days can be administered at the discretion of the investigator.
IVMP With Oral Prednisolone Taper	Intravenous methylprednisolone (IVMP) 1g/day for 6 days followed by an oral taper over 2 months. If necessary, additional cycles of 1 g IVMP daily for 3 to 5 days can be administered at any time.

Participant Flow: Overall Study

	Pulsed IVMP	IVMP With Oral Prednisolone Taper
STARTED	2	1
		[1]

COMPLETED	0	1
NOT COMPLETED	2	0
Withdrawal by Subject	1	0
Death	1	0

[1] completed treatment with study drug

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Pulsed IVMP	Intravenous methylprednisolone (IVMP) 1 g/day administered the first 3 days of each weekly cycle, and repeated for 3 additional cycles (totaling 4 cycles). If necessary, 2 additional weekly cycles of 1 g IVMP daily for 3 days can be administered at the discretion of the investigator.
IVMP With Oral Prednisolone Taper	Intravenous methylprednisolone (IVMP) 1g/day for 6 days followed by an oral taper over 2 months. If necessary, additional cycles of 1 g IVMP daily for 3 to 5 days can be administered at any time.
Total	Total of all reporting groups

Baseline Measures

	Pulsed IVMP	IVMP With Oral Prednisolone Taper	Total
Number of Participants [units: participants]	2	1	3
Age [units: participants]			
<=18 years	0	0	0
Between 18 and 65 years	2	1	3
>=65 years	0	0	0
Gender [units: participants]			
Female	2	1	3
Male	0	0	0

Outcome Measures

Hide All Outcome Measures

1. Primary: Time Course Change in Functional Status Based on Karnofsky Performance Status Index Through 6 Months Following Completion of Plasma Exchange (PLEX) [Time Frame: Baseline up to 6 months]

Measure Type	Primary
Measure Title	Time Course Change in Functional Status Based on Karnofsky Performance Status Index Through 6 Months Following

	Completion of Plasma Exchange (PLEX)
Measure Description	The Karnofsky Performance Status Index (KPSI) is an assessment tool intended to assist clinicians and caretakers in gauging a patient's functional status and ability to carry out activities of daily living. A KPSI of 100=normal, no complaints, no evidence of disease; 90=able to carry on normal activity, minor signs or symptoms of disease; 80=normal activity with effort, some signs or symptoms of disease; 70=cares for self, unable to carry on normal activity or do active work; 60=requires occasional assistance but is able to care for most personal needs; 50=requires considerable assistance and frequent medical care; 40=disabled, requires special care and assistance; 30=severely disabled, hospitalization is indicated, although death is not imminent; 20=very sick, hospitalization is necessary, active support treatment is necessary; 10=moribund, fatal processes progressing rapidly; 0=dead.
Time Frame	Baseline up to 6 months
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was stopped prematurely due to lack of enrollment; this analysis was not performed.

Reporting Groups

	Description
Pulsed IVMP	Intravenous methylprednisolone (IVMP) 1 g/day administered the first 3 days of each weekly cycle, and repeated for 3 additional cycles (totaling 4 cycles). If necessary, 2 additional weekly cycles of 1 g IVMP daily for 3 days can be administered at the discretion of the investigator.
IVMP With Oral Prednisolone Taper	Intravenous methylprednisolone (IVMP) 1g/day for 6 days followed by an oral taper over 2 months. If necessary, additional cycles of 1 g IVMP daily for 3 to 5 days can be administered at any time.

Measured Values

	Pulsed IVMP	IVMP With Oral Prednisolone Taper
Number of Participants Analyzed [units: participants]	0	0
Time Course Change in Functional Status Based on Karnofsky Performance Status Index Through 6 Months Following Completion of Plasma Exchange (PLEX)		

No statistical analysis provided for Time Course Change in Functional Status Based on Karnofsky Performance Status Index Through 6 Months Following Completion of Plasma Exchange (PLEX)

2. Primary: Number of Participants Who Survived at 6 Months Following Completion of Plasma Exchange (PLEX) [Time Frame: 6 months]

Measure Type	Primary
Measure Title	Number of Participants Who Survived at 6 Months Following Completion of Plasma Exchange (PLEX)
Measure Description	Following the completion of rapid removal of natalizumab using PLEX or equivalent.
Time Frame	6 months
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Pulsed IVMP	Intravenous methylprednisolone (IVMP) 1 g/day administered the first 3 days of each weekly cycle, and repeated for 3 additional cycles (totaling 4 cycles). If necessary, 2 additional weekly cycles of 1 g IVMP daily for 3 days can be administered at the discretion of the investigator.
IVMP With Oral Prednisolone Taper	Intravenous methylprednisolone (IVMP) 1g/day for 6 days followed by an oral taper over 2 months. If necessary, additional cycles of 1 g IVMP daily for 3 to 5 days can be administered at any time.

Measured Values

	Pulsed IVMP	IVMP With Oral Prednisolone Taper
Number of Participants Analyzed [units: participants]	2	1
Number of Participants Who Survived at 6 Months Following Completion of Plasma Exchange (PLEX) [units: participants]	1	1

No statistical analysis provided for Number of Participants Who Survived at 6 Months Following Completion of Plasma Exchange (PLEX)

3. Primary: Number of Participants With Adverse Events (AEs) and Serious Adverse Events (SAEs) [Time Frame: from the first dose of study treatment through the end of the treatment period (6 months) + a 4-week post-treatment period]

Measure Type	Primary
Measure Title	Number of Participants With Adverse Events (AEs) and Serious Adverse Events (SAEs)
Measure Description	AE=any untoward medical occurrence in a participant administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. SAE=any untoward medical occurrence that at any dose: results in death; in the view of the Investigator, places the participant at immediate risk of death (a life-threatening event); however, this does not include an event that, had it occurred in a more severe form, might have caused death; requires hospitalization or prolongation of existing hospitalization; results in persistent or significant disability/incapacity; or results in a congenital anomaly/birth defect. An SAE may also be any other medically important event that, in the opinion of the Investigator, may jeopardize the participant or may require intervention to prevent one of the other outcomes listed in the definition above.
Time Frame	from the first dose of study treatment through the end of the treatment period (6 months) + a 4-week post-treatment period
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Pulsed IVMP	Intravenous methylprednisolone (IVMP) 1 g/day administered the first 3 days of each weekly cycle, and repeated for 3 additional cycles (totaling 4 cycles). If necessary, 2 additional weekly cycles of 1 g IVMP daily for 3 days can be administered at the discretion of the investigator.
IVMP With Oral Prednisolone Taper	Intravenous methylprednisolone (IVMP) 1g/day for 6 days followed by an oral taper over 2 months. If necessary, additional cycles of 1 g IVMP daily for 3 to 5 days can be administered at any time.

Measured Values

	Pulsed	IVMP With Oral Prednisolone

	IVMP	Taper
Number of Participants Analyzed [units: participants]	2	1
Number of Participants With Adverse Events (AEs) and Serious Adverse Events (SAEs) [units: participants]		
AEs	2	1
SAEs	2	1

No statistical analysis provided for Number of Participants With Adverse Events (AEs) and Serious Adverse Events (SAEs)

4. Primary: Severity of AEs and SAEs [Time Frame: from the first dose of study treatment through the end of the treatment period (6 months) + a 4-week post-treatment period]

Measure Type	Primary
Measure Title	Severity of AEs and SAEs
Measure Description	AEs and SAEs were categorized as mild, moderate or severe according to the following criteria: Mild=barely noticeable to participant or does not make participant uncomfortable; does not influence performance or functioning; prescription drug not ordinarily needed for relief of symptom(s) but may be given because of personality of participant. Moderate=of a sufficient severity to make participant uncomfortable; performance of daily activity is influenced; participant is able to continue in study; treatment for symptom(s) may be needed. Severe=symptoms cause severe discomfort; symptoms cause incapacity or significant impact on participant's daily life; severity may cause cessation of treatment with study treatment; treatment for symptom(s) may be given and/or participant hospitalized. Please see Outcome Measure 3 for AE and SAE definitions.
Time Frame	from the first dose of study treatment through the end of the treatment period (6 months) + a 4-week post-treatment period
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Pulsed IVMP	Intravenous methylprednisolone (IVMP) 1 g/day administered the first 3 days of each weekly cycle, and repeated for 3 additional cycles (totaling 4 cycles). If necessary, 2 additional weekly cycles of 1 g IVMP daily for 3 days can be administered at the discretion of the investigator.
IVMP With Oral Prednisolone Taper	Intravenous methylprednisolone (IVMP) 1g/day for 6 days followed by an oral taper over 2 months. If necessary, additional cycles of 1 g IVMP daily for 3 to 5 days can be administered at any time.

Measured Values

	Pulsed IVMP	IVMP With Oral Prednisolone Taper
Number of Participants Analyzed [units: participants]	2	1
Severity of AEs and SAEs [units: events]		
Mild SAE	1	1
Moderate SAE	1	1
Severe SAE	2	0

Mild AE	3	5
Moderate AE	3	1
Severe AE	0	0

No statistical analysis provided for Severity of AEs and SAEs

5. Primary: Time Course Change in the Global Clinical Impression of Improvement (GCI-I) Scale [Time Frame: Screening to 6 months following completion of PLEX (participants began treatment with intravenous methylprednisolone (IVMP) within 2 weeks after PLEX [or equivalent]).]

Measure Type	Primary
Measure Title	Time Course Change in the Global Clinical Impression of Improvement (GCI-I) Scale
Measure Description	The GCI-I scale is a 7-point scale that assesses how much the participant's illness has improved or worsened relative to a baseline state at the beginning of the intervention, and rates it as: 1=very much improved; 2=much improved; 3=minimally improved; 4=no change; 5=minimally worse; 6=much worse; 7=very much worse.
Time Frame	Screening to 6 months following completion of PLEX (participants began treatment with intravenous methylprednisolone (IVMP) within 2 weeks after PLEX [or equivalent]).
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was stopped prematurely due to lack of enrollment; this analysis was not performed.

Reporting Groups

	Description
Pulsed IVMP	Intravenous methylprednisolone (IVMP) 1 g/day administered the first 3 days of each weekly cycle, and repeated for 3 additional cycles (totaling 4 cycles). If necessary, 2 additional weekly cycles of 1 g IVMP daily for 3 days can be administered at the discretion of the investigator.
IVMP With Oral Prednisolone Taper	Intravenous methylprednisolone (IVMP) 1g/day for 6 days followed by an oral taper over 2 months. If necessary, additional cycles of 1 g IVMP daily for 3 to 5 days can be administered at any time.

Measured Values

	Pulsed IVMP	IVMP With Oral Prednisolone Taper
Number of Participants Analyzed [units: participants]	0	0
Time Course Change in the Global Clinical Impression of Improvement (GCI-I) Scale		

No statistical analysis provided for Time Course Change in the Global Clinical Impression of Improvement (GCI-I) Scale

6. Primary: Time Course Change in Cerebral Dysfunction Using the Symbol Digit Modalities Test (SDMT) [Time Frame: Screening to 6 months following completion of PLEX (participants began treatment with IVMP within 2 weeks after PLEX [or equivalent]).]

Measure Type	Primary
Measure Title	Time Course Change in Cerebral Dysfunction Using the Symbol Digit Modalities Test (SDMT)
Measure Description	The SDMT measures the time to pair abstract symbols with specific numbers. The test requires elements of attention, visuoperceptual processing, working memory, and psychomotor speed. The score is the number of correctly coded items from 0-110 in 90 seconds. The total score provides a measure of the speed and accuracy of symbol-digit substitution.

Time Frame	Screening to 6 months following completion of PLEX (participants began treatment with IVMP within 2 weeks after PLEX [or equivalent]).
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was stopped prematurely due to lack of enrollment; this analysis was not performed.

Reporting Groups

	Description
Pulsed IVMP	Intravenous methylprednisolone (IVMP) 1 g/day administered the first 3 days of each weekly cycle, and repeated for 3 additional cycles (totaling 4 cycles). If necessary, 2 additional weekly cycles of 1 g IVMP daily for 3 days can be administered at the discretion of the investigator.
IVMP With Oral Prednisolone Taper	Intravenous methylprednisolone (IVMP) 1g/day for 6 days followed by an oral taper over 2 months. If necessary, additional cycles of 1 g IVMP daily for 3 to 5 days can be administered at any time.

Measured Values

	Pulsed IVMP	IVMP With Oral Prednisolone Taper
Number of Participants Analyzed [units: participants]	0	0
Time Course Change in Cerebral Dysfunction Using the Symbol Digit Modalities Test (SDMT)		

No statistical analysis provided for Time Course Change in Cerebral Dysfunction Using the Symbol Digit Modalities Test (SDMT)

7. Primary: Time Course Changes in Brain Magnetic Resonance Imaging (MRI) [Time Frame: Screening to 6 months following completion of PLEX (participants began treatment with IVMP within 2 weeks after PLEX [or equivalent]).]

Measure Type	Primary
Measure Title	Time Course Changes in Brain Magnetic Resonance Imaging (MRI)
Measure Description	The brain MRI data collected included: progressive multifocal leukoencephalopathy (PML) lesion localization, T2 hyperintense lesion volume, and signs of cerebral edema.
Time Frame	Screening to 6 months following completion of PLEX (participants began treatment with IVMP within 2 weeks after PLEX [or equivalent]).
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was stopped prematurely due to lack of enrollment; this analysis was not performed.

Reporting Groups

	Description
Pulsed IVMP	Intravenous methylprednisolone (IVMP) 1 g/day administered the first 3 days of each weekly cycle, and repeated for 3 additional cycles (totaling 4 cycles). If necessary, 2 additional weekly cycles of 1 g IVMP daily for 3 days can be administered at the discretion of the investigator.

IVMP With Oral Prednisolone Taper	Intravenous methylprednisolone (IVMP) 1g/day for 6 days followed by an oral taper over 2 months. If necessary, additional cycles of 1 g IVMP daily for 3 to 5 days can be administered at any time.

Measured Values

	Pulsed IVMP	IVMP With Oral Prednisolone Taper
Number of Participants Analyzed [units: participants]	0	0
Time Course Changes in Brain Magnetic Resonance Imaging (MRI)		

No statistical analysis provided for Time Course Changes in Brain Magnetic Resonance Imaging (MRI)

8. Primary: Time Course Change in Magnetoencephalography (MEG) Results [Time Frame: Screening to 6 months following completion of PLEX (participants began treatment with IVMP within 2 weeks after PLEX [or equivalent]).]

Measure Type	Primary
Measure Title	Time Course Change in Magnetoencephalography (MEG) Results
Measure Description	MEG was used to map brain activity.
Time Frame	Screening to 6 months following completion of PLEX (participants began treatment with IVMP within 2 weeks after PLEX [or equivalent]).
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was stopped prematurely due to lack of enrollment; no data on this endpoint was collected.

Reporting Groups

	Description
Pulsed IVMP	Intravenous methylprednisolone (IVMP) 1 g/day administered the first 3 days of each weekly cycle, and repeated for 3 additional cycles (totaling 4 cycles). If necessary, 2 additional weekly cycles of 1 g IVMP daily for 3 days can be administered at the discretion of the investigator.
IVMP With Oral Prednisolone Taper	Intravenous methylprednisolone (IVMP) 1g/day for 6 days followed by an oral taper over 2 months. If necessary, additional cycles of 1 g IVMP daily for 3 to 5 days can be administered at any time.

Measured Values

	Pulsed IVMP	IVMP With Oral Prednisolone Taper
Number of Participants Analyzed [units: participants]	0	0
Time Course Change in Magnetoencephalography (MEG) Results		

No statistical analysis provided for Time Course Change in Magnetoencephalography (MEG) Results

9. Primary: Time Course Change in Clinical Laboratory Values [Time Frame: Screening to 6 months following completion of PLEX (participants began treatment with IVMP within 2 weeks after PLEX [or equivalent]).]

Measure Type	Primary
Measure Title	Time Course Change in Clinical Laboratory Values
Measure Description	Clinical laboratory values included chemokines, cytokines, C-reactive protein (CRP), John Cunningham (JC) virus load, and

	cell count in cerebrospinal fluid.
Time Frame	Screening to 6 months following completion of PLEX (participants began treatment with IVMP within 2 weeks after PLEX [or equivalent]).
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was stopped prematurely due to lack of enrollment; this analysis was not performed.

Reporting Groups

	Description
Pulsed IVMP	Intravenous methylprednisolone (IVMP) 1 g/day administered the first 3 days of each weekly cycle, and repeated for 3 additional cycles (totaling 4 cycles). If necessary, 2 additional weekly cycles of 1 g IVMP daily for 3 days can be administered at the discretion of the investigator.
IVMP With Oral Prednisolone Taper	Intravenous methylprednisolone (IVMP) 1g/day for 6 days followed by an oral taper over 2 months. If necessary, additional cycles of 1 g IVMP daily for 3 to 5 days can be administered at any time.

Measured Values

	Pulsed IVMP	IVMP With Oral Prednisolone Taper
Number of Participants Analyzed [units: participants]	0	0
Time Course Change in Clinical Laboratory Values		

No statistical analysis provided for Time Course Change in Clinical Laboratory Values

10. Primary: Time Course Elimination of Serum Natalizumab Concentration Following Plasma Exchange (PLEX) or Equivalent [Time Frame: Baseline up to 6 months]

Measure Type	Primary
Measure Title	Time Course Elimination of Serum Natalizumab Concentration Following Plasma Exchange (PLEX) or Equivalent
Measure Description	No text entered.
Time Frame	Baseline up to 6 months
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was stopped prematurely due to lack of enrollment; this analysis was not performed.

Reporting Groups

	Description
Pulsed IVMP	Intravenous methylprednisolone (IVMP) 1 g/day administered the first 3 days of each weekly cycle, and repeated for 3 additional cycles (totaling 4 cycles). If necessary, 2 additional weekly cycles of 1 g IVMP daily for 3 days can be administered at the discretion of the investigator.
IVMP With Oral Prednisolone Taper	Intravenous methylprednisolone (IVMP) 1g/day for 6 days followed by an oral taper over 2 months. If necessary, additional cycles of 1 g IVMP daily for 3 to 5 days can be administered at any time.

Measured Values

	Pulsed IVMP	IVMP With Oral Prednisolone Taper
Number of Participants Analyzed [units: participants]	0	0
Time Course Elimination of Serum Natalizumab Concentration Following Plasma Exchange (PLEX) or Equivalent		

No statistical analysis provided for Time Course Elimination of Serum Natalizumab Concentration Following Plasma Exchange (PLEX) or Equivalent

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	AEs and SAEs were collected from the first dose of study treatment through the end of the treatment period (6 months) + a 4-week post-treatment period.
Additional Description	No text entered.

Reporting Groups

	Description
Pulsed IVMP	Intravenous methylprednisolone (IVMP) 1 g/day administered the first 3 days of each weekly cycle, and repeated for 3 additional cycles (totaling 4 cycles). If necessary, 2 additional weekly cycles of 1 g IVMP daily for 3 days can be administered at the discretion of the investigator.
IVMP With Oral Prednisolone Taper	Intravenous methylprednisolone (IVMP) 1g/day for 6 days followed by an oral taper over 2 months. If necessary, additional cycles of 1 g IVMP daily for 3 to 5 days can be administered at any time.

Serious Adverse Events

	Pulsed IVMP	IVMP With Oral Prednisolone Taper
Total, serious adverse events		
# participants affected / at risk	2/2 (100.00%)	1/1 (100.00%)
Immune system disorders		
Immune Reconstitution Syndrome † [1]		
# participants affected / at risk	0/2 (0.00%)	1/1 (100.00%)
Infections and infestations		
Progressive Multifocal Leukoencephalopathy † [1]		
# participants affected / at risk	1/2 (50.00%)	1/1 (100.00%)
Urinary Tract Infection † [1]		
# participants affected / at risk	1/2 (50.00%)	0/1 (0.00%)
Nervous system disorders		
Grand Mal Convulsion † [1]		
# participants affected / at risk	1/2 (50.00%)	0/1 (0.00%)
Respiratory, thoracic and mediastinal disorders		
Pneumonia Aspiration † [1]		
# participants affected / at risk	1/2 (50.00%)	0/1 (0.00%)

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 15.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	AEs and SAEs were collected from the first dose of study treatment through the end of the treatment period (6 months) + a 4-week post-treatment period.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	0%

Reporting Groups

	Description
Pulsed IVMP	Intravenous methylprednisolone (IVMP) 1 g/day administered the first 3 days of each weekly cycle, and repeated for 3 additional cycles (totaling 4 cycles). If necessary, 2 additional weekly cycles of 1 g IVMP daily for 3 days can be administered at the discretion of the investigator.
IVMP With Oral Prednisolone Taper	Intravenous methylprednisolone (IVMP) 1g/day for 6 days followed by an oral taper over 2 months. If necessary, additional cycles of 1 g IVMP daily for 3 to 5 days can be administered at any time.

Other Adverse Events

	Pulsed IVMP	IVMP With Oral Prednisolone Taper
Total, other (not including serious) adverse events		
# participants affected / at risk	2/2 (100.00%)	1/1 (100.00%)
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	1/2 (50.00%)	0/1 (0.00%)
Gastrointestinal disorders		
Anal Fissure † 1		
# participants affected / at risk	1/2 (50.00%)	0/1 (0.00%)
Diarrhoea † 1		
# participants affected / at risk	1/2 (50.00%)	0/1 (0.00%)
Vomiting † 1		
# participants affected / at risk	1/2 (50.00%)	0/1 (0.00%)
Infections and infestations		
Pneumonia † 1		
# participants affected / at risk	1/2 (50.00%)	0/1 (0.00%)
Progressive Multifocal Leukoencephalopathy † 1		
# participants affected / at risk	0/2 (0.00%)	1/1 (100.00%)
Metabolism and nutrition disorders		
Hypokalaemia † 1		
# participants affected / at risk	0/2 (0.00%)	1/1 (100.00%)
Psychiatric disorders		
† 1		

Insomnia		
# participants affected / at risk	0/2 (0.00%)	1/1 (100.00%)
Skin and subcutaneous tissue disorders		
Skin Haemorrhage † 1		
# participants affected / at risk	1/2 (50.00%)	0/1 (0.00%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 15.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.
There IS an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is less than or equal to 60 days. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is more than 60 days but less than or equal to 180 days. The sponsor cannot require changes to the communication and cannot extend the embargo. ☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. Restriction Description: Our agreement is subject to confidentiality but generally the PI can publish, for noncommercial purposes only, results and methods of the trial, but no other Sponsor Confidential Information. PI must give Sponsor no less than 60 days to review any manuscript for a proposed publication and must delay publication for up to an additional 90 days thereafter if Sponsor needs to file any patent application to protect any of Sponsor's intellectual property contained in the proposed publication.

Results Point of Contact:

Name/Title: Biogen Idec Study Medical Director
Organization: Biogen Idec
e-mail: clinicaltrials@biogenidec.com

No publications provided

Responsible Party:	Biogen Idec
ClinicalTrials.gov Identifier:	NCT01211665 History of Changes
Other Study ID Numbers:	101JC404, 2010-020369-26
Study First Received:	July 29, 2010
Results First Received:	July 23, 2014
Last Updated:	August 26, 2014
Health Authority:	United States: Institutional Review Board

Germany: Ethics Commission
Germany: Federal Institute for Drugs and Medical Devices
United States: Food and Drug Administration