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Trial record **1 of 1** for: 26866138MMY2031

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A Study of Bortezomib, Cyclophosphamide, and Dexamethasone in Patients With Untreated Multiple Myeloma and Planned for a High Dose Chemotherapy

This study has been completed.

Sponsor:
Janssen-Cilag G.m.b.H

Information provided by (Responsible Party):
Janssen-Cilag G.m.b.H

ClinicalTrials.gov Identifier:
NCT00833560

First received: January 23, 2009
Last updated: November 11, 2014
Last verified: November 2014
History of Changes

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Results First Received: October 30, 2013

Study Type:	Interventional
Study Design:	Endpoint Classification: Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Multiple Myeloma
Interventions:	Drug: Cyclophosphamide Drug: Bortezomib Drug: Dexamethasone

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
401 participants were enrolled at 41 study sites in Germany.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Out of 401 participants, 399 participants were treated in both the Parts. Out of 399 participants, 395 participants were evaluated as 4 participants who had received cyclophophamide dose of greater than 1350 mg/m^2 per cycle in Part 1 were excluded.

Reporting Groups

	Description
Cyclophosphamide + Bortezomib + Dexamethasone	Cyclophosphamide + Bortezomib + Dexamethasone for three 21-day cycles

Participant Flow: Overall Study

	Cyclophosphamide + Bortezomib + Dexamethasone
STARTED	**395**
COMPLETED	**353**

NOT COMPLETED	**42**
Toxicity	**13**
Adverse Event	**11**
Protocol Violation	**6**
Lack of Efficacy	**4**
Death	**2**
Pregression of other disease	**1**
Not specified	**5**

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
Cyclophosphamide + Bortezomib + Dexamethasone	Cyclophosphamide + Bortezomib + Dexamethasone for three 21-day cycles

Baseline Measures

	Cyclophosphamide + Bortezomib + Dexamethasone
Number of Participants [units: participants]	**395**
Age [units: Years] Mean (Standard Deviation)	**52.4 (6.5)**
Age, Customized [units: Participants]	
Between 20 and 39 years	**17**
Between 40 and 49 years	**109**
Between 50 and 60 years	**253**
>65 years	**16**
Gender [units: Participants]	
Female	**166**
Male	**229**

Outcome Measures

Hide All Outcome Measures

1. Primary: Participants With Complete Response (CR) + Partial Response (PR) (Efficacy Set) [Time Frame: Up to Day 63]

Measure Type	Primary

Measure Title	Participants With Complete Response (CR) + Partial Response (PR) (Efficacy Set)
Measure Description	CR and PR are defined by the local investigator according to the current European Group for Blood and Marrow Transplantation (EBMT) criteria. According to EBMT criteria, CR is defined as the absence of serum and urine monoclonal paraprotein + no increase in size or number of lytic bone lesions; and PR is defined as not all CR criteria + 50 percentage or more reduction in serum monoclonal paraprotein.
Time Frame	Up to Day 63
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.
Efficacy analysis set: Participants of the safety analysis set (who received bortezomib at least once independently of accordance to the protocol) who had an evaluable investigator based assessment of success of therapy at the end of study visit (ie, assessment by local investigator as CR, PR, minimal response, stable disease, progressive disease).

Reporting Groups

	Description
Cyclophosphamide + Bortezomib + Dexamethasone	Cyclophosphamide + Bortezomib + Dexamethasone for three 21-day cycles

Measured Values

	Cyclophosphamide + Bortezomib + Dexamethasone
Number of Participants Analyzed [units: participants]	**391**
Participants With Complete Response (CR) + Partial Response (PR) (Efficacy Set) [units: Participants]	**334**

Statistical Analysis 1 for Participants With Complete Response (CR) + Partial Response (PR) (Efficacy Set)

Groups [1]	Cyclophosphamide + Bortezomib + Dexamethasone
Method [2]	Two - sided binomial test
P Value [3]	<0.0001
Percentage of participants with response [4]	85.4
95% Confidence Interval	81.5 to 88.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Participants With Complete Response (CR) + Partial Response (PR) (Per-protocol Analysis Set) [Time Frame: Up to Day 63]

Measure Type	Secondary
Measure Title	Participants With Complete Response (CR) + Partial Response (PR) (Per-protocol Analysis Set)
Measure Description	CR and PR are defined by the local investigator according to the current European Group for Blood and Marrow Transplantation (EBMT) criteria. According to EBMT criteria, CR is defined as the absence of serum and urine monoclonal paraprotein + no increase in size or number of lytic bone lesions; and PR is defined as not all CR criteria + 50 percentage or more reduction in serum monoclonal paraprotein.
Time Frame	Up to Day 63
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.
Per-protocol analysis set: It includes the participants who completed the entire clinical study without major protocol violations.

Reporting Groups

	Description
Cyclophosphamide + Bortezomib + Dexamethasone	Cyclophosphamide + Bortezomib + Dexamethasone for three 21-day cycles

Measured Values

	Cyclophosphamide + Bortezomib + Dexamethasone
Number of Participants Analyzed [units: participants]	**324**
Participants With Complete Response (CR) + Partial Response (PR) (Per-protocol Analysis Set) [units: Participants]	**284**

Statistical Analysis 1 for Participants With Complete Response (CR) + Partial Response (PR) (Per-protocol Analysis Set)

Groups [1]	Cyclophosphamide + Bortezomib + Dexamethasone
Method [2]	Two-sided binomial test
P Value [3]	<0.0001
Percentage of participants with response [4]	87.7
95% Confidence Interval	83.6 to 91.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

3. Secondary: Percentage of Participants With Complete Response + Partial Response in Relation to Cytogenetic Subgroups (Efficacy Set) [

Time Frame: Up to Day 63]

Measure Type	Secondary
Measure Title	Percentage of Participants With Complete Response + Partial Response in Relation to Cytogenetic Subgroups (Efficacy Set)
Measure Description	Response rate was defined as the percentage of participants with response of combined CR+PR according to the EBMT criteria. As per the EBMT criteria, CR is defined as the absence of serum and urine monoclonal paraprotein and no increase in size or number of lytic bone lesions; PR is defined as not all CR criteria and 50 percentage or more reduction in serum monoclonal paraprotein. Percentage of participants with complete or partial response that carried the indicated cytogenetic marker is reported. Same participant could count in more than one category due to multiple responses possible
Time Frame	Up to Day 63
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.
Efficacy analysis set. N (number of participants analyzed) signifies participants with complete or partial response. "n" signifies number of participants who were evaluable for each specified category (participants that carried the indicated cytogenetic marker).

Reporting Groups

	Description
Cyclophosphamide + Bortezomib + Dexamethasone	Cyclophosphamide + Bortezomib + Dexamethasone for three 21-day cycles

Measured Values

	Cyclophosphamide + Bortezomib + Dexamethasone
Number of Participants Analyzed [units: participants]	**334**
Percentage of Participants With Complete Response + Partial Response in Relation to Cytogenetic Subgroups (Efficacy Set) [units: Percentage of participants]	
13q- (n=112)	**90.2**
t (4;14) (n=38)	**89.5**
17p- (n=31)	**74.2**
Other (n=104)	**87.5**
No changes (n=102)	**84.3**

No statistical analysis provided for Percentage of Participants With Complete Response + Partial Response in Relation to Cytogenetic Subgroups (Efficacy Set)

4. Secondary: Percentage of Participants With Complete Response + Partial Response in Relation to Cytogenetic Subgroups (Per-protocol Set) [Time Frame: Up to Day 63]

Measure Type	Secondary
Measure Title	Percentage of Participants With Complete Response + Partial Response in Relation to Cytogenetic Subgroups (Per-protocol Set)
Measure Description	Response rate was defined as the percentage of participants with response of combined CR+PR according to the EBMT criteria. As per the EBMT criteria, CR is defined as the absence of serum and urine monoclonal paraprotein and no increase in size or number of lytic bone lesions; PR is defined as not all CR criteria and 50 percentage or more

	reduction in serum monoclonal paraprotein. Percentage of participants with complete or partial response that carried the indicated cytogenetic marker is reported. Same participant could count in more than one category due to multiple responses possible.
Time Frame	Up to Day 63
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.
Per-protocol analysis set. N (number of participants analyzed) signifies participants with complete or partial response. "n" signifies number of participants who were evaluable for each specified category (participants that carried the indicated cytogenetic marker).

Reporting Groups

	Description
Cyclophosphamide + Bortezomib + Dexamethasone	Cyclophosphamide + Bortezomib + Dexamethasone for three 21-day cycles

Measured Values

	Cyclophosphamide + Bortezomib + Dexamethasone
Number of Participants Analyzed [units: participants]	**284**
Percentage of Participants With Complete Response + Partial Response in Relation to Cytogenetic Subgroups (Per-protocol Set) [units: Percentage of participants]	
13q- (n=92)	**92.4**
t (4;14) (n=34)	**91.2**
17p- (n=24)	**87.5**
Other (n=87)	**88.5**
No changes (n=87)	**85.1**

No statistical analysis provided for Percentage of Participants With Complete Response + Partial Response in Relation to Cytogenetic Subgroups (Per-protocol Set)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	From date of inform consent signed to 30 days after the last bortezomib dosing or, if earlier, until start of an alternative myeloma therapy.
Additional Description	No text entered.

Reporting Groups

	Description
Cyclophosphamide + Bortezomib + Dexamethasone	Cyclophosphamide + Bortezomib + Dexamethasone for three 21-day cycles

Serious Adverse Events

	Cyclophosphamide + Bortezomib + Dexamethasone
Total, serious adverse events	
# participants affected / at risk	**103/395 (26.08%)**

Blood and lymphatic system disorders	
Leukopenia † 1	
# participants affected / at risk	**11/395 (2.78%)**
# events	**12**
Neutropenia † 1	
# participants affected / at risk	**4/395 (1.01%)**
# events	**5**
Febrile neutropenia † 1	
# participants affected / at risk	**3/395 (0.76%)**
# events	**3**
Hyperviscosity syndrome † 1	
# participants affected / at risk	**2/395 (0.51%)**
# events	**2**
Granulocytopenia † 1	
# participants affected / at risk	**1/395 (0.25%)**
# events	**1**
Cardiac disorders	
Cardiac failure † 1	
# participants affected / at risk	**4/395 (1.01%)**
# events	**4**
Cardiac failure acute † 1	
# participants affected / at risk	**1/395 (0.25%)**
# events	**1**
Cardiovascular disorder † 1	
# participants affected / at risk	**1/395 (0.25%)**
# events	**1**
Ear and labyrinth disorders	
Vertigo † 1	
# participants affected / at risk	**2/395 (0.51%)**
# events	**2**
Presbyacusis † 1	
# participants affected / at risk	**1/395 (0.25%)**
# events	**1**
Tinnitus † 1	
# participants affected / at risk	**1/395 (0.25%)**
# events	**1**
Eye disorders	
Diplopia † 1	
# participants affected / at risk	**1/395 (0.25%)**
# events	**1**
Gastrointestinal disorders	
Diarrhoea † 1	
# participants affected / at risk	**5/395 (1.27%)**
# events	**5**
Constipation † 1	
# participants affected / at risk	**4/395 (1.01%)**
# events	**4**

Nausea † 1	
# participants affected / at risk	**4/395 (1.01%)**
# events	**5**
Vomiting † 1	
# participants affected / at risk	**3/395 (0.76%)**
# events	**3**
Abdominal pain † 1	
# participants affected / at risk	**2/395 (0.51%)**
# events	**2**
Anal fissure † 1	
# participants affected / at risk	**1/395 (0.25%)**
# events	**1**
Flatulence † 1	
# participants affected / at risk	**1/395 (0.25%)**
# events	**1**
Gastric haemorrhage † 1	
# participants affected / at risk	**1/395 (0.25%)**
# events	**1**
Gastric ulcer haemorrhage † 1	
# participants affected / at risk	**1/395 (0.25%)**
# events	**1**
Ileus † 1	
# participants affected / at risk	**1/395 (0.25%)**
# events	**1**
Intestinal dilatation † 1	
# participants affected / at risk	**1/395 (0.25%)**
# events	**1**
Periodontitis † 1	
# participants affected / at risk	**1/395 (0.25%)**
# events	**1**
General disorders	
Pyrexia † 1	
# participants affected / at risk	**14/395 (3.54%)**
# events	**15**
Disease progression † 1	
# participants affected / at risk	**3/395 (0.76%)**
# events	**3**
Asthenia † 1	
# participants affected / at risk	**2/395 (0.51%)**
# events	**2**
General physical health deterioration † 1	
# participants affected / at risk	**2/395 (0.51%)**
# events	**2**
Pain † 1	
# participants affected / at risk	**2/395 (0.51%)**
# events	**2**
Chills † 1	
# participants affected / at risk	**1/395 (0.25%)**
# events	**1**

Fatigue † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Multi-organ failure † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Sudden cardiac death † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Hepatobiliary disorders	
Cholecystitis † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Cholelithiasis † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Hepatitis † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Infections and infestations	
Pneumonia † 1	
# participants affected / at risk	15/395 (3.80%)
# events	16
Herpes zoster † 1	
# participants affected / at risk	3/395 (0.76%)
# events	3
Sepsis † 1	
# participants affected / at risk	3/395 (0.76%)
# events	3
Urinary tract infection † 1	
# participants affected / at risk	3/395 (0.76%)
# events	3
Bronchitis † 1	
# participants affected / at risk	2/395 (0.51%)
# events	2
Bacterial sepsis † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Bronchiolitis † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Bronchitis bacterial † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Bronchopneumonia † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Device related infection † 1	

# participants affected / at risk	1/395 (0.25%)
# events	1
Encephalitis herpes † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Endocarditis bacterial † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Erysipelas † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Febrile infection † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Gastroenteritis † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Gastroenteritis adenovirus † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Herpes simplex † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Herpes virus infection † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Pseudomembranous colitis † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Septic shock † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Pneumonia viral † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Injury, poisoning and procedural complications	
Humerus fracture † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Investigations	
C-reactive protein increased † 1	
# participants affected / at risk	2/395 (0.51%)
# events	2
Alanine aminotransferase increased † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Aspartate aminotransferase increased † 1	

# participants affected / at risk	1/395 (0.25%)
# events	1
Blood creatinine increased † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Blood glucose increased † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Blood immunoglobulin G increased † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Blood potassium increased † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Body temperature increased † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Metabolism and nutrition disorders	
Diabetes mellitus † 1	
# participants affected / at risk	2/395 (0.51%)
# events	2
Hypokalaemia † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Hyponatraemia † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Musculoskeletal and connective tissue disorders	
Back pain † 1	
# participants affected / at risk	2/395 (0.51%)
# events	2
Bone pain † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Intervertebral disc protrusion † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Joint instability † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Osteolysis † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Pathological fracture † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Nervous system disorders	
Polyneuropathy † 1	

# participants affected / at risk	4/395 (1.01%)
# events	4
Convulsion † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Dizziness † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Loss of consciousness † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Neuralgia † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Neuropathy peripheral † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Paraparesis † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Psychiatric disorders	
Anxiety † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Suicide attempt † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Renal and urinary disorders	
Renal failure † 1	
# participants affected / at risk	3/395 (0.76%)
# events	3
Haematuria † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Respiratory, thoracic and mediastinal disorders	
Acute respiratory distress syndrome † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Alveolitis allergic † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Dyspnoea † 1	
# participants affected / at risk	1/395 (0.25%)
# events	2
Epiglottic oedema † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Interstitial lung disease † 1	

# participants affected / at risk	1/395 (0.25%)
# events	1
Pulmonary embolism † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Respiratory failure † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Skin and subcutaneous tissue disorders	
Skin disorder † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Skin reaction † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Vascular disorders	
Hypertensive crisis † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Hypotension † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1
Thrombosis † 1	
# participants affected / at risk	1/395 (0.25%)
# events	1

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA version 9.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	From date of inform consent signed to 30 days after the last bortezomib dosing or, if earlier, until start of an alternative myeloma therapy.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Cyclophosphamide + Bortezomib + Dexamethasone	Cyclophosphamide + Bortezomib + Dexamethasone for three 21-day cycles

Other Adverse Events

	Cyclophosphamide + Bortezomib + Dexamethasone
Total, other (not including serious) adverse events	
# participants affected / at risk	**392/395 (99.24%)**
Blood and lymphatic system disorders	

Leukopenia † 1	
# participants affected / at risk	**211/395 (53.42%)**
# events	**680**
Thrombocytopenia † 1	
# participants affected / at risk	**129/395 (32.66%)**
# events	**277**
Anaemia † 1	
# participants affected / at risk	**77/395 (19.49%)**
# events	**132**
Neutropenia † 1	
# participants affected / at risk	**32/395 (8.10%)**
# events	**53**
Gastrointestinal disorders	
Nausea † 1	
# participants affected / at risk	**105/395 (26.58%)**
# events	**141**
Constipation † 1	
# participants affected / at risk	**86/395 (21.77%)**
# events	**98**
Diarrhoea † 1	
# participants affected / at risk	**73/395 (18.48%)**
# events	**88**
Vomiting † 1	
# participants affected / at risk	**50/395 (12.66%)**
# events	**63**
Flatulence † 1	
# participants affected / at risk	**25/395 (6.33%)**
# events	**26**
General disorders	
Oedema peripheral † 1	
# participants affected / at risk	**79/395 (20.00%)**
# events	**105**
Fatigue † 1	
# participants affected / at risk	**76/395 (19.24%)**
# events	**85**
Pyrexia † 1	
# participants affected / at risk	**56/395 (14.18%)**
# events	**70**
Asthenia † 1	
# participants affected / at risk	**41/395 (10.38%)**
# events	**46**
Oedema † 1	
# participants affected / at risk	**28/395 (7.09%)**
# events	**32**
Pain † 1	
# participants affected / at risk	**28/395 (7.09%)**
# events	**33**
Infections and infestations	

Nasopharyngitis † 1	
# participants affected / at risk	**47/395 (11.90%)**
# events	**50**
Rhinitis † 1	
# participants affected / at risk	**30/395 (7.59%)**
# events	**31**
Investigations	
C-reactive protein increased † 1	
# participants affected / at risk	**39/395 (9.87%)**
# events	**47**
Weight increased † 1	
# participants affected / at risk	**38/395 (9.62%)**
# events	**43**
Haemoglobin decreased † 1	
# participants affected / at risk	**28/395 (7.09%)**
# events	**73**
Alanine aminotransferase increased † 1	
# participants affected / at risk	**22/395 (5.57%)**
# events	**24**
Metabolism and nutrition disorders	
Hypokalaemia † 1	
# participants affected / at risk	**25/395 (6.33%)**
# events	**30**
Hyperglycaemia † 1	
# participants affected / at risk	**23/395 (5.82%)**
# events	**27**
Musculoskeletal and connective tissue disorders	
Back pain † 1	
# participants affected / at risk	**46/395 (11.65%)**
# events	**56**
Bone pain † 1	
# participants affected / at risk	**32/395 (8.10%)**
# events	**34**
Pain in extremity † 1	
# participants affected / at risk	**29/395 (7.34%)**
# events	**38**
Nervous system disorders	
Paraesthesia † 1	
# participants affected / at risk	**63/395 (15.95%)**
# events	**75**
Headache † 1	
# participants affected / at risk	**54/395 (13.67%)**
# events	**62**
Polyneuropathy † 1	
# participants affected / at risk	**51/395 (12.91%)**
# events	**68**
Dizziness † 1	
# participants affected / at risk	**48/395 (12.15%)**

# events	55
Hypoaesthesia † 1	
# participants affected / at risk	27/395 (6.84%)
# events	30
Dysgeusia † 1	
# participants affected / at risk	20/395 (5.06%)
# events	20
Psychiatric disorders	
Sleep disorder † 1	
# participants affected / at risk	46/395 (11.65%)
# events	53
Respiratory, thoracic and mediastinal disorders	
Cough † 1	
# participants affected / at risk	45/395 (11.39%)
# events	49
Dyspnoea † 1	
# participants affected / at risk	28/395 (7.09%)
# events	31
Pharyngolaryngeal pain † 1	
# participants affected / at risk	20/395 (5.06%)
# events	21
Skin and subcutaneous tissue disorders	
Night sweats † 1	
# participants affected / at risk	36/395 (9.11%)
# events	39
Erythema † 1	
# participants affected / at risk	28/395 (7.09%)
# events	31
Rash † 1	
# participants affected / at risk	22/395 (5.57%)
# events	22
Vascular disorders	
Hypertension † 1	
# participants affected / at risk	28/395 (7.09%)
# events	33

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 9.1

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.

Results Point of Contact:

Name/Title: Therapeutic Areas Director
Organization: Jan-Cil Germany
phone: +49 2137 955-492

Responsible Party:	Janssen-Cilag G.m.b.H
ClinicalTrials.gov Identifier:	NCT00833560 History of Changes
Other Study ID Numbers:	CR005242 **26866138MMY2031** (Other Identifier: Janssen-Cilag G.m.b.H, Germany) 2005-003902-27 (EudraCT Number)
Study First Received:	January 23, 2009
Results First Received:	October 30, 2013
Last Updated:	November 11, 2014
Health Authority:	Germany: Federal Institute for Drugs and Medical Devices Germany: Ethics Commission

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