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Trial record **1 of 1** for: 26866138MMY3021
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A Study of Subcutaneous and Intravenous VELCADE in Patients With Previously Treated Multiple Myeloma

This study has been completed.

Sponsor:
Millennium Pharmaceuticals, Inc.

Collaborator:
Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Information provided by (Responsible Party):
Millennium Pharmaceuticals, Inc.

ClinicalTrials.gov Identifier:
NCT00722566

First received: July 23, 2008
Last updated: October 6, 2011
Last verified: October 2011
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: August 30, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Multiple Myeloma
Interventions:	Drug: VELCADE Administered by subcutaneous injection Drug: VELCADE Administered by intravenous infusion

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
VELCADE Subcutaneous	VELCADE 1.3 mg/m^2 administered by subcutaneous injection on Days 1, 4, 8, and 11 of a 3-week cycle for 8 cycles.
VELCADE Intravenous	VELCADE 1.3 mg/m^2 administered by intravenous infusion on Days 1, 4, 8, and 11 of a 3-week cycle for 8 cycles.

Participant Flow: Overall Study

	VELCADE Subcutaneous	VELCADE Intravenous

STARTED	**148** [1]	**74**
COMPLETED	**81** [2]	**39** [2]
NOT COMPLETED	**67**	**35**

[1] One patient randomized and not dosed
[2] Completed 8 cycles

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
VELCADE Subcutaneous	VELCADE 1.3 mg/m^2 administered by subcutaneous injection on Days 1, 4, 8, and 11 of a 3-week cycle for 8 cycles.
VELCADE Intravenous	VELCADE 1.3 mg/m^2 administered by intravenous infusion on Days 1, 4, 8, and 11 of a 3-week cycle for 8 cycles.
Total	Total of all reporting groups

Baseline Measures

	VELCADE Subcutaneous	**VELCADE Intravenous**	**Total**
Number of Participants [units: participants]	**148**	**74**	**222**
Age [units: participants]			
<=18 years	**0**	**0**	**0**
Between 18 and 65 years	**74**	**37**	**111**
>=65 years	**74**	**37**	**111**
Age [units: years] Mean (Standard Deviation)	**64.3 (8.96)**	**64.0 (12.11)**	**64.2 (10.09)**
Gender [units: participants]			
Female	**74**	**27**	**101**
Male	**74**	**47**	**121**
Region of Enrollment [units: participants]			
France	**22**	**14**	**36**
Belgium	**7**	**5**	**12**
Germany	**2**	**4**	**6**
Netherlands	**6**	**4**	**10**
United Kingdom	**6**	**3**	**9**
Ukraine	**51**	**17**	**68**

Russian Federation	**26**	**9**	**35**
Poland	**20**	**7**	**27**
Argentina	**5**	**8**	**13**
India	**3**	**3**	**6**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Patients With Overall Response (Complete Response + Partial Response) [Time Frame: Over 4 cycles (prior to the addition of dexamethasone)]

Measure Type	Primary
Measure Title	Number of Patients With Overall Response (Complete Response + Partial Response)
Measure Description	Disease response was measured according to European Group for Blood and Marrow Transplantation (EBMT) criteria with the addition of the response categories of nCR and VGPR. Complete response requires disappearance of monoclonal protein from the blood and urine and <5% plasma cells in the bone marrow on at least 2 determinations for a minimum of 6 weeks. Partial Response requires ≥50% reduction in serum m-protein for at least 2 determinations at least 6 weeks apart and if present, reduction in 24-hour urinary light chain excretion by either ≥90% or to <200 mg
Time Frame	Over 4 cycles (prior to the addition of dexamethasone)
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.
The response-evaluable population was defined as subjects who received at least 1 dose of study drug and had measurable, secretory multiple myeloma, defined as a serum monoclonal IgG or IgM of ≥10 g/L or a serum monoclonal IgA or IgE ≥5 g/L, or a serum monoclonal IgD of ≥0.5g/L, or urine M-protein of ≥200 mg/24 hours, at study entry.

Reporting Groups

	Description
VELCADE Subcutaneuous	VELCADE 1.3 mg/m^2 administered by subcutaneous injection on Days 1, 4, 8, and 11 of a 3-week cycle for 8 cycles.
VELCADE Intravenous	VELCADE 1.3 mg/m^2 administered by intravenous injection on Days 1, 4, 8, and 11 of a 3-week cycle for 8 cycles.

Measured Values

	VELCADE Subcutaneuous	**VELCADE Intravenous**
Number of Participants Analyzed [units: participants]	**145**	**73**
Number of Patients With Overall Response (Complete Response + Partial Response) [units: Participants]	**61**	**31**

Statistical Analysis 1 for Number of Patients With Overall Response (Complete Response + Partial Response)

Groups [1]	All groups

Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	Farrrington and Manning
P Value [4]	0.00201
ORR_SQ - 0.6 ORR_IV [5]	16.8
95% Confidence Interval	6.1 to 27.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	In this trial, non-inferiority is defined as retaining 60% of the IV (active control) treatment effect as measured by ORR. The non-inferiority hypothesis can be stated as: H0: ORRSC – 0.60 ORRIV <0 vs. H1: ORRSC – 0.60 ORRIV ≥0 (non-inferiority).
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	Assuming ORRs are 35.5% for both SC and IV, one-sided alpha level of 0.025, and approximately 80% power, approximately 216 subjects (144 SC:72 IV) are needed to show non-inferiority of SC to IV VELCADE.
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	CONOR P. FARRINGTON AND GODFREY MANNING STATISTICS IN MEDICINE, VOL. 9, 1447-1454(1990).
[4]	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.
[5]	Other relevant estimation information:
	No text entered.

2. Secondary: Number of Patients With Complete Response [Time Frame: Over 4 cycles (prior to the addition of dexamethasone)]

Measure Type	Secondary
Measure Title	Number of Patients With Complete Response
Measure Description	Disease response was measured according to European Group for Blood and Marrow Transplantation (EBMT) criteria with the addition of the response categories of nCR and VGPR. Complete response requires disappearance of monoclonal protein from the blood and urine and <5% plasma cells in the bone marrow on at least 2 determinations for a minimum of 6 weeks.
Time Frame	Over 4 cycles (prior to the addition of dexamethasone)
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.
The response-evaluable population was defined as subjects who received at least 1 dose of study drug and had measurable, secretory multiple myeloma, defined as a serum monoclonal IgG or IgM of ≥10 g/L or a serum monoclonal IgA or IgE ≥5 g/L, or a serum monoclonal IgD of ≥0.5g/L, or urine M-protein of ≥200 mg/24 hours, at study entry.

Reporting Groups

	Description
VELCADE Subcutaneous	VELCADE 1.3 mg/m^2 administered by subcutaneous injection on Days 1, 4, 8, and 11 of a 3-week cycle for 8 cycles.
VELCADE Intravenous	VELCADE 1.3 mg/m^2 administered by intravenous infusion on Days 1, 4, 8, and 11 of a 3-week cycle for 8 cycles.

Measured Values

	VELCADE Subcutaneous	VELCADE Intravenous
Number of Participants Analyzed [units: participants]	145	73
Number of Patients With Complete Response [units: Participants]	9	6

No statistical analysis provided for Number of Patients With Complete Response

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
VELCADE Subcutaneous	VELCADE 1.3 mg/m^2 administered by subcutaneous injection on Days 1, 4, 8, and 11 of a 3-week cycle for 8 cycles.
VELCADE Intravenous	VELCADE 1.3 mg/m^2 administered by intravenous infusion on Days 1, 4, 8, and 11 of a 3-week cycle for 8 cycles.

Serious Adverse Events

	VELCADE Subcutaneous	VELCADE Intravenous
Total, serious adverse events		
# participants affected / at risk	53/147 (36.05%)	26/74 (35.14%)
Blood and lymphatic system disorders		
Anemia † 1		
# participants affected / at risk	0/147 (0.00%)	1/74 (1.35%)
Neutropenia † 1		
# participants affected / at risk	1/147 (0.68%)	1/74 (1.35%)
Splenomegaly † 1		
# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)
Thrombocytopenia † 1		
# participants affected / at risk	1/147 (0.68%)	1/74 (1.35%)
Cardiac disorders		
Angina Pectoris † 1		
# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)
Arrhythmia † 1		
# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)
Arteriosclerosis coronary artery † 1		
# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)
Atrial Fibrillation † 1		
# participants affected / at risk	2/147 (1.36%)	0/74 (0.00%)
Bradyarrhythmia † 1		

# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)
Cardiac Arrest † 1		
# participants affected / at risk	0/147 (0.00%)	1/74 (1.35%)
Cardiac failure † 1		
# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)
Cardiac failure acute † 1		
# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)
Coronary artery insufficiency † 1		
# participants affected / at risk	0/147 (0.00%)	1/74 (1.35%)
Myocardial infarction † 1		
# participants affected / at risk	0/147 (0.00%)	1/74 (1.35%)
Supraventricular tachycardia † 1		
# participants affected / at risk	0/147 (0.00%)	1/74 (1.35%)
Tachycardia paroxysmal † 1		
# participants affected / at risk	0/147 (0.00%)	1/74 (1.35%)
Ear and labyrinth disorders		
Acute vestibular syndrome † 1		
# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)
Gastrointestinal disorders		
Abdominal discomfort † 1		
# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)
Abdominal pain † 1		
# participants affected / at risk	1/147 (0.68%)	1/74 (1.35%)
Diarrhoea † 1		
# participants affected / at risk	3/147 (2.04%)	3/74 (4.05%)
Haematemesis † 1		
# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)
Intestinal obstruction † 1		
# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)
Mallory-Weiss syndrome † 1		
# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)
Nausea † 1		
# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)
Pancreatitis chronic † 1		
# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)
Vomiting † 1		
# participants affected / at risk	1/147 (0.68%)	1/74 (1.35%)
General disorders		
Asthenia † 1		
# participants affected / at risk	2/147 (1.36%)	0/74 (0.00%)
Chest pain † 1		
# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)
Malaise † 1		
# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)

Multi-organ failure † 1		
# participants affected / at risk	**1/147 (0.68%)**	**1/74 (1.35%)**
Pain † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Pyrexia † 1		
# participants affected / at risk	**4/147 (2.72%)**	**0/74 (0.00%)**
Sudden death † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Hepatitis C † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Hepatobiliary disorders		
Cholecystitis acute † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Hepatic failure † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Hepatic function abnormal † 1		
# participants affected / at risk	**0/147 (0.00%)**	**1/74 (1.35%)**
Hepatitis toxic † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Infections and infestations		
Bronchitis † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Escherichia sepsis † 1		
# participants affected / at risk	**0/147 (0.00%)**	**1/74 (1.35%)**
Herpes Zoster † 1		
# participants affected / at risk	**2/147 (1.36%)**	**0/74 (0.00%)**
Injection site abscess † 1		
# participants affected / at risk	**0/147 (0.00%)**	**1/74 (1.35%)**
Pneumocystis jiroveci pneumonia † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Pneumonia † 1		
# participants affected / at risk	**9/147 (6.12%)**	**5/74 (6.76%)**
Sepsis † 1		
# participants affected / at risk	**0/147 (0.00%)**	**1/74 (1.35%)**
Sinusitis † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Skin infection † 1		
# participants affected / at risk	**0/147 (0.00%)**	**1/74 (1.35%)**
Urinary tract infection † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Injury, poisoning and procedural complications		
Humerus fracture † 1		
# participants affected / at risk	**1/147 (0.68%)**	**1/74 (1.35%)**
Perianal haematoma † 1		

# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)
Metabolism and nutrition disorders		
Decreased appetite † 1		
# participants affected / at risk	2/147 (1.36%)	0/74 (0.00%)
Dehydration † 1		
# participants affected / at risk	2/147 (1.36%)	0/74 (0.00%)
Hypercalcemia † 1		
# participants affected / at risk	1/147 (0.68%)	1/74 (1.35%)
Hypokalaemia † 1		
# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)
Tumour lysis syndrome † 1		
# participants affected / at risk	2/147 (1.36%)	1/74 (1.35%)
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	0/147 (0.00%)	1/74 (1.35%)
Back pain † 1		
# participants affected / at risk	0/147 (0.00%)	1/74 (1.35%)
Pathological fracture † 1		
# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Colon cancer † 1		
# participants affected / at risk	0/147 (0.00%)	1/74 (1.35%)
Lung neoplasm † 1		
# participants affected / at risk	0/147 (0.00%)	1/74 (1.35%)
Plasmacytoma † 1		
# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)
Nervous system disorders		
Brain oedema † 1		
# participants affected / at risk	0/147 (0.00%)	1/74 (1.35%)
Cerebrovascular disorder † 1		
# participants affected / at risk	0/147 (0.00%)	1/74 (1.35%)
Encephalopathy † 1		
# participants affected / at risk	0/147 (0.00%)	1/74 (1.35%)
Ischaemic stroke † 1		
# participants affected / at risk	0/147 (0.00%)	1/74 (1.35%)
Neuralgia † 1		
# participants affected / at risk	2/147 (1.36%)	0/74 (0.00%)
Paraparesis † 1		
# participants affected / at risk	2/147 (1.36%)	0/74 (0.00%)
Paraplegia † 1		
# participants affected / at risk	1/147 (0.68%)	0/74 (0.00%)
Peripheral neuropathy motor † 1		
# participants affected / at risk	2/147 (1.36%)	1/74 (1.35%)

Peripheral sensorimotor neuropathy † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Peripheral sensory neuropathy † 1		
# participants affected / at risk	**2/147 (1.36%)**	**2/74 (2.70%)**
Spinal cord compression † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Syncope † 1		
# participants affected / at risk	**0/147 (0.00%)**	**1/74 (1.35%)**
Toxic encephalopathy † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Vascular encephalopathy † 1		
# participants affected / at risk	**0/147 (0.00%)**	**1/74 (1.35%)**
Psychiatric disorders		
Confusional state † 1		
# participants affected / at risk	**0/147 (0.00%)**	**1/74 (1.35%)**
Neurosis † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Renal and urinary disorders		
Dysuria † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Haematuria † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Renal failure † 1		
# participants affected / at risk	**3/147 (2.04%)**	**2/74 (2.70%)**
Renal failure acute † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Renal impairment † 1		
# participants affected / at risk	**0/147 (0.00%)**	**1/74 (1.35%)**
Urinary retention † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Reproductive system and breast disorders		
Vulval ulceration † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Allergic bronchitis † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Bronchospasm † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	**2/147 (1.36%)**	**1/74 (1.35%)**
Cough † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Dyspnoea † 1		
# participants affected / at risk	**2/147 (1.36%)**	**1/74 (1.35%)**

Lung disorder † 1		
# participants affected / at risk	**0/147 (0.00%)**	**1/74 (1.35%)**
Nasal congestion † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Pleural effusion † 1		
# participants affected / at risk	**0/147 (0.00%)**	**1/74 (1.35%)**
Pleurisy † 1		
# participants affected / at risk	**1/147 (0.68%)**	**1/74 (1.35%)**
Vascular disorders		
Haematoma † 1		
# participants affected / at risk	**1/147 (0.68%)**	**0/74 (0.00%)**
Hypotension † 1		
# participants affected / at risk	**0/147 (0.00%)**	**1/74 (1.35%)**
Orthostatic hypotension † 1		
# participants affected / at risk	**2/147 (1.36%)**	**1/74 (1.35%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (13.0)

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
VELCADE Subcutaneous	VELCADE 1.3 mg/m^2 administered by subcutaneous injection on Days 1, 4, 8, and 11 of a 3-week cycle for 8 cycles.
VELCADE Intravenous	VELCADE 1.3 mg/m^2 administered by intravenous infusion on Days 1, 4, 8, and 11 of a 3-week cycle for 8 cycles.

Other Adverse Events

	VELCADE Subcutaneous	**VELCADE Intravenous**
Total, other (not including serious) adverse events		
# participants affected / at risk	**112/147 (76.19%)**	**66/74 (89.19%)**
Blood and lymphatic system disorders		
Leukopenia † 1		
# participants affected / at risk	**29/147 (19.73%)**	**16/74 (21.62%)**
Eye disorders		
Chalazion † 1		
# participants affected / at risk	**2/147 (1.36%)**	**4/74 (5.41%)**
Gastrointestinal disorders		

Abdominal pain upper † 1		
# participants affected / at risk	**3/147 (2.04%)**	**8/74 (10.81%)**
Constipation † 1		
# participants affected / at risk	**21/147 (14.29%)**	**11/74 (14.86%)**
Dyspepsia † 1		
# participants affected / at risk	**4/147 (2.72%)**	**7/74 (9.46%)**
General disorders		
Chills † 1		
# participants affected / at risk	**6/147 (4.08%)**	**4/74 (5.41%)**
Fatigue † 1		
# participants affected / at risk	**17/147 (11.56%)**	**15/74 (20.27%)**
Oedema peripheral † 1		
# participants affected / at risk	**9/147 (6.12%)**	**6/74 (8.11%)**
Infections and infestations		
Nasopharyngitis † 1		
# participants affected / at risk	**4/147 (2.72%)**	**6/74 (8.11%)**
Upper respiratory tract infection † 1		
# participants affected / at risk	**7/147 (4.76%)**	**7/74 (9.46%)**
Investigations		
Weight decreased † 1		
# participants affected / at risk	**22/147 (14.97%)**	**2/74 (2.70%)**
Metabolism and nutrition disorders		
Hyperglycaemia † 1		
# participants affected / at risk	**7/147 (4.76%)**	**5/74 (6.76%)**
Hyperkalaemia † 1		
# participants affected / at risk	**7/147 (4.76%)**	**1/74 (1.35%)**
Musculoskeletal and connective tissue disorders		
Bone pain † 1		
# participants affected / at risk	**12/147 (8.16%)**	**2/74 (2.70%)**
Muscle spasms † 1		
# participants affected / at risk	**4/147 (2.72%)**	**5/74 (6.76%)**
Musculoskeletal pain † 1		
# participants affected / at risk	**2/147 (1.36%)**	**4/74 (5.41%)**
Pain in extremity † 1		
# participants affected / at risk	**8/147 (5.44%)**	**8/74 (10.81%)**
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	**10/147 (6.80%)**	**2/74 (2.70%)**
Headache † 1		
# participants affected / at risk	**5/147 (3.40%)**	**8/74 (10.81%)**
Paraesthesia † 1		
# participants affected / at risk	**9/147 (6.12%)**	**6/74 (8.11%)**
Psychiatric disorders		

Insomnia † 1		
# participants affected / at risk	**18/147 (12.24%)**	**8/74 (10.81%)**
Skin and subcutaneous tissue disorders		
Pruritis † 1		
# participants affected / at risk	**7/147 (4.76%)**	**2/74 (2.70%)**
Rash † 1		
# participants affected / at risk	**10/147 (6.80%)**	**5/74 (6.76%)**
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	**14/147 (9.52%)**	**3/74 (4.05%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (13.0)

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 **NOT** 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.

Results Point of Contact:

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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Moreau P, Pylypenko H, Grosicki S, Karamanesht I, Leleu X, Rekhtman G, Masliak Z, Robak P, Esseltine DL, Feng H, Deraedt W, van de Velde H, Arnulf B. Subcutaneous versus intravenous bortezomib in patients with relapsed multiple myeloma: subanalysis of patients with renal impairment in the phase III MMY-3021 study. Haematologica. 2015 May;100(5):e207-10. doi: 10.3324/haematol.2014.118182. Epub 2015 Jan 16.

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