Study of the Combination of VELCADE, Rituximab, Cyclophosphamide, Doxorubicin, and Prednisone or Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone in Patients With Newly Diagnosed Non-Germinal Center B-Cell Subtype of Diffuse Large B-Cell Lymphoma

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:
NCT01040871

First received: December 29, 2009
Last updated: December 11, 2013
Last verified: December 2013
History of Changes

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

Results First Received: July 5, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Diffuse Large B-Cell Lymphoma
Interventions:	Drug: VELCADE Drug: Rituximab Drug: Cyclophosphamide Drug: Doxorubicin Drug: Prednisone Drug: Vincristine

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

164 participants were randomized, three participants did not receive study treatment (2 in the VR-CAP and 1 in the R-CHOP arm) for a total of 161 treated.

Reporting Groups

	Description
VR-CAP	VR-CAP arm received rituximab 375 mg/m2 IV on Day 1, cyclophosphamide 750 mg/m2 IV on Day 1, doxorubicin 50 mg/m2 IV on Day 1, VELCADE 1.3 mg/m2 IV on Days 1, 4, 8, and 11, and prednisone 100 mg/m2 orally on Days 1 through 5 of each 21-day (3-week) cycle for up to 6 cycles.
R-CHOP	R-CHOP received rituximab 375 mg/m2IV on Day 1, cyclophosphamide 750 mg/m2 IV on Day 1, doxorubicin 50 mg/m2 IV on Day 1, vincristine 1.4 mg/m2 (maximum total of 2 mg) IV on Day 1, and prednisone 100 mg/m2 orally on Days 1 through 5 of each 21-day (3-week) cycle for up to 6 cycles.Prednisone

Participant Flow: Overall Study

	VR-CAP	R-CHOP
STARTED	**84** [1]	**80** [1]
COMPLETED	**71**	**73**
NOT COMPLETED	**13**	**7**
Adverse Event	**6**	**2**
Withdrawal by Subject	**2**	**0**
Death	**1**	**3**
Lack of Efficacy	**1**	**1**
drug supply issue	**1**	**0**
Randomized and Not Treated	**2**	**1**

[1] Intent to Treat, Randomized

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.
Intent to Treat, Randomized

Reporting Groups

	Description
VR-CAP	VELCADE, Rituximab, Cyclophosphamide, Doxorubicin and Prednisone
R-CHOP	Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone
Total	Total of all reporting groups

Baseline Measures

	VR-CAP	R-CHOP	Total
Number of Participants [units: participants]	**84**	**80**	**164**
Age			

[units: years] Mean (Standard Deviation)	**56.5 (15.00)**	**57.8 (13.83)**	**57.2 (14.41)**
Gender [units: participants]			
Female	**43**	**33**	**76**
Male	**41**	**47**	**88**
Region of Enrollment [units: participants]			
Russian Federation	**22**	**14**	**36**
Turkey	**4**	**12**	**16**
Korea, Republic of	**6**	**6**	**12**
Malaysia	**5**	**3**	**8**
Canada	**3**	**3**	**6**
India	**2**	**4**	**6**
Brazil	**2**	**3**	**5**
Argentina	**2**	**1**	**3**
Singapore	**2**	**1**	**3**
Mexico	**0**	**1**	**1**
Germany	**13**	**8**	**21**
Portugal	**5**	**7**	**12**
Italy	**2**	**6**	**8**
Czech Republic	**3**	**4**	**7**
Spain	**5**	**2**	**7**
France	**2**	**4**	**6**
Belgium	**4**	**1**	**5**
Ireland	**2**	**0**	**2**

Outcome Measures

Hide All Outcome Measures

1. Primary: Complete Response (CR) Rate [Time Frame: 6 cycles]

Measure Type	Primary
Measure Title	Complete Response (CR) Rate
Measure Description	Complete response was evaluated by an Independent Radiology Review Committee using available computed tomography (CT) and positron emission tomography (PET) scans collected at Baseline, end of cycle 3, and end of cycle 6 (or end of treatment) based on the Revised Response Criteria for Malignant Lymphoma. 1. Complete disappearance of all detectable clinical evidence of disease and disease-related symptoms if present before therapy. 2. PET scan was negative. 3. The spleen and/or liver, if enlarged before therapy on the basis of physical examination or CT scan, was not palpable on physical examination and was considered normal size by imaging studies; all splenic and hepatic nodules related to lymphomas disappeared.

	4. If bone marrow was involved before treatment, the infiltrate cleared on repeated bone marrow biopsy. 5. No new sites of disease were detected.
Time Frame	6 cycles
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.
All randomized subjects with non-GCB DLBCL who received at least 1 dose of any study drug, had at least 1 measurable lesion at baseline, and had at least 1 post-baseline response assessment

Reporting Groups

	Description
VR-CAP	VELCADE, Rituximab, Cyclophosphamide, Doxorubicin and Prednisone
R-CHOP	Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone

Measured Values

	VR-CAP	**R-CHOP**
Number of Participants Analyzed [units: participants]	**76**	**74**
Complete Response (CR) Rate [units: percentage of participants] Number (90% Confidence Interval)	**64.5 (55.4 to 73.5)**	**63.5 (54.3 to 72.7)**

Statistical Analysis 1 for Complete Response (CR) Rate

Groups [1]	All groups
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.915
Odds Ratio (OR) [4]	1.038
95% Confidence Interval	0.529 to 2.037

[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:
	Stratified by IPI score
[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:
	Odds ratio: VR-CAP CR rate relative to R-CHOP CR rate

2. Secondary: Overall Response Rate [Time Frame: 6 cycles]

Measure Type	Secondary
Measure Title	Overall Response Rate
Measure Description	Overall response = Complete Response (CR) + Partial Response (PR) Response was evaluated by an Independent Radiology Review Committee using available computed tomography (CT) and positron emission tomography (PET) scans collected at Baseline, end of cycle 3, and end of cycle 6 (or end of treatment) based on the Revised Response Criteria for Malignant Lymphoma. Complete Response: see primary endpoint Partial Response: At least a 50% decrease in the sum of the product of the diameters (SPD) of up to 6 of the largest dominant nodes or nodal masses.
Time Frame	6 cycles
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.
All randomized subjects with non-GCB DLBCL who received at least 1 dose of any study drug, had at least 1 measurable lesion at baseline, and had at least 1 post-baseline response assessment

Reporting Groups

	Description
VR-CAP	VELCADE, Rituximab, Cyclophosphamide, Doxorubicin and Prednisone
R-CHOP	Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone

Measured Values

	VR-CAP	**R-CHOP**
Number of Participants Analyzed [units: participants]	**76**	**74**
Overall Response Rate [units: percentage of participants] Number (90% Confidence Interval)	**93.4 (88.7 to 98.1)**	**98.6 (96.4 to 100.0)**

No statistical analysis provided for Overall Response Rate

3. Secondary: Rate of Durable Response [Time Frame: Median follow up approx. 12 months]

Measure Type	Secondary
Measure Title	Rate of Durable Response
Measure Description	Proportion of subjects who achieved a CR or PR with duration of at least 6 months. Duration of response (CR or PR) was calculated from the date of initial documentation of a response to the date of first documented evidence of disease progression or death due to disease progression. Response was evaluated by an Independent Radiology Review Committee using available computed tomography (CT) and positron emission tomography (PET) scans collected at Baseline, end of cycle 3, end of cycle 6 (or end of treatment) based on the Revised Response Criteria for Malignant Lymphoma.
Time Frame	Median follow up approx. 12 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.
No text entered.

Reporting Groups

	Description
VR-CAP	VELCADE, Rituximab, Cyclophosphamide, Doxorubicin and Prednisone
R-CHOP	Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone

Measured Values

	VR-CAP	**R-CHOP**
Number of Participants Analyzed [units: participants]	**76**	**74**
Rate of Durable Response [units: percentage of participants] Number (95% Confidence Interval)	**53.9 (44.5 to 63.4)**	**67.6 (58.6 to 76.5)**

No statistical analysis provided for Rate of Durable Response

4. Secondary: Rate of Durable Complete Response [Time Frame: Median follow up approx 12 months]

Measure Type	Secondary
Measure Title	Rate of Durable Complete Response
Measure Description	Proportion of subjects who achieved a CR with duration of at least 6 months
Time Frame	Median follow up approx 12 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.
No text entered.

Reporting Groups

	Description
VR-CAP	VELCADE, Rituximab, Cyclophosphamide, Doxorubicin and Prednisone
R-CHOP	Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone

Measured Values

	VR-CAP	**R-CHOP**
Number of Participants Analyzed [units: participants]	**76**	**74**

Rate of Durable Complete Response [units: percentage of participants] Number (95% Confidence Interval)	**44.7 (35.3 to 54.1)**	**47.3 (37.7 to 56.9)**

No statistical analysis provided for Rate of Durable Complete Response

5. Secondary: Subsequent Anti-lymphoma Therapy Rate at 1-year [Time Frame: 1 year]

Measure Type	Secondary
Measure Title	Subsequent Anti-lymphoma Therapy Rate at 1-year
Measure Description	Kaplan-meier estimate of subsequent anti-lymphoma therapy at 1-year. Time to subsequent anti-lymphoma therapy was measured from the date of randomization to the start date of new treatment. Death due to disease progression prior to subsequent therapy was considered as an event. Otherwise, time to next anti-lymphoma treatment was censored at the date of death or the last date known to be alive.
Time Frame	1 year
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.
Intent to Treat Population

Reporting Groups

	Description
VR-CAP	VELCADE, Rituximab, Cyclophosphamide, Doxorubicin and Prednisone
R-CHOP	Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone

Measured Values

	VR-CAP	**R-CHOP**
Number of Participants Analyzed [units: participants]	**84**	**80**
Subsequent Anti-lymphoma Therapy Rate at 1-year [units: percentage of participants] Number (95% Confidence Interval)	**71.1 (57.9 to 80.8)**	**80.2 (68.8 to 87.9)**

No statistical analysis provided for Subsequent Anti-lymphoma Therapy Rate at 1-year

6. Secondary: Progression-free Survival (PFS)Rate at 1-year [Time Frame: 1 year]

Measure Type	Secondary
Measure Title	Progression-free Survival (PFS)Rate at 1-year
Measure Description	Kaplan-meier estimate of progression-free survival at 1-year. Progression-free survival was defined as the interval between the date of randomization and the date of first documented evidence of disease progression or death.
Time Frame	1 year

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.
Intent to Treat Population

Reporting Groups

	Description
VR-CAP	VELCADE, Rituximab, Cyclophosphamide, Doxorubicin and Prednisone
R-CHOP	Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone

Measured Values

	VR-CAP	**R-CHOP**
Number of Participants Analyzed [units: participants]	**84**	**80**
Progression-free Survival (PFS)Rate at 1-year [units: percentage of partipants] Number (95% Confidence Interval)	**78.9 (67.2 to 86.8)**	**83.9 (72.7 to 90.8)**

No statistical analysis provided for Progression-free Survival (PFS)Rate at 1-year

7. Secondary: Overall Survival Rate at 1-year [Time Frame: 1 year]

Measure Type	Secondary
Measure Title	Overall Survival Rate at 1-year
Measure Description	Kaplan-meier estimate of overall survival at 1-year measured from date of randomization.
Time Frame	1 year
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.
Intent to Treat Population

Reporting Groups

	Description
VR-CAP	VELCADE, Rituximab, Cyclophosphamide, Doxorubicin and Prednisone
R-CHOP	Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone

Measured Values

	VR-CAP	**R-CHOP**
Number of Participants Analyzed [units: participants]	**84**	**80**

Overall Survival Rate at 1-year [units: percentage of partipants] Number (95% Confidence Interval)	**94.1 (84.6 to 97.8)**	**84.2 (73.2 to 91.0)**

No statistical analysis provided for Overall Survival Rate at 1-year

8. Secondary: Change in Fatigue and Patient Utility Scores [Time Frame: 18-24 months]

Results not yet reported. **Anticipated Reporting Date:** No text entered. **Safety Issue:** No

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Number at risk is based on the safety population defined as patients who were randomized and received at least one dose of study drug. A total of 164 participants were randomized and 3 participants did not receive study treatment (2 in the VR-CAP arm, 1 in the R-CHOP arm) for a total of 161 treated (82 in the VR-CAP arm, 79 in the R-CHOP arm).

Reporting Groups

	Description
VR-CAP	VELCADE, Rituximab, Cyclophosphamide, Doxorubicin and Prednisone
R-CHOP	Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone

Serious Adverse Events

	VR-CAP	R-CHOP
Total, serious adverse events		
# participants affected / at risk	**31/82 (37.80%)**	**27/79 (34.18%)**
Blood and lymphatic system disorders		
Febrile neutropenia † 1		
# participants affected / at risk	**7/82 (8.54%)**	**7/79 (8.86%)**
Neutropenia † 1		
# participants affected / at risk	**4/82 (4.88%)**	**5/79 (6.33%)**
Febrile bone marrow aplasia † 1		
# participants affected / at risk	**0/82 (0.00%)**	**1/79 (1.27%)**
Leukopenia † 1		
# participants affected / at risk	**1/82 (1.22%)**	**0/79 (0.00%)**
Lymphadenopathy † 1		
# participants affected / at risk	**0/82 (0.00%)**	**1/79 (1.27%)**
Splenomegaly † 1		
# participants affected / at risk	**1/82 (1.22%)**	**0/79 (0.00%)**
Thrombocytopenia † 1		
# participants affected / at risk	**1/82 (1.22%)**	**0/79 (0.00%)**
Cardiac disorders		

Cardiac arrest † 1		
# participants affected / at risk	1/82 (1.22%)	1/79 (1.27%)
Arrhythmia † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Atrial flutter † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Cardiac failure acute † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Extrasystoles † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Pericarditis † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Ear and labyrinth disorders		
Vertigo † 1		
# participants affected / at risk	2/82 (2.44%)	0/79 (0.00%)
Eye disorders		
Retinal detachment † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	1/82 (1.22%)	1/79 (1.27%)
Diarrhoea † 1		
# participants affected / at risk	2/82 (2.44%)	0/79 (0.00%)
Gastrointestinal haemorrhage † 1		
# participants affected / at risk	1/82 (1.22%)	1/79 (1.27%)
Nausea † 1		
# participants affected / at risk	1/82 (1.22%)	1/79 (1.27%)
Vomiting † 1		
# participants affected / at risk	1/82 (1.22%)	1/79 (1.27%)
Dyphagia † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Gastritis † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Ileus paralytic † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Small intestinal obstruction † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Upper gastrointestinal haemorrhage † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
General disorders		
Pyrexia † 1		

# participants affected / at risk	5/82 (6.10%)	0/79 (0.00%)
Asthenia † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Chest pain † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
General physical health deterioration † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Malaise † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Performance status decreased † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Infections and infestations		
Pneumonia † 1		
# participants affected / at risk	4/82 (4.88%)	3/79 (3.80%)
Device related infection † 1		
# participants affected / at risk	1/82 (1.22%)	1/79 (1.27%)
Gastroenteritis † 1		
# participants affected / at risk	1/82 (1.22%)	1/79 (1.27%)
Lung infection † 1		
# participants affected / at risk	2/82 (2.44%)	0/79 (0.00%)
Septic shock † 1		
# participants affected / at risk	1/82 (1.22%)	1/79 (1.27%)
Abscess neck † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Hepatitis viral † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Herpes zoster † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Oral candidiasis † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Pneumocystis jiroveci pneumonia † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Respiratory tract infection † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Sepsis † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Skin infection † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Upper respiratory tract infection † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Injury, poisoning and procedural complications		

Contusion † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Investigations		
International normalised ratio increased † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Metabolism and nutrition disorders		
Hyperphosphatasaemia † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Hypokalemia † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Hypomagnesaemia † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Musculoskeletal and connective tissue disorders		
Arthritis † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Lumbar spinal stenosis † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Muscle fatigue † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Muscular weakness † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Nervous system disorders		
Cerebrovascular accident † 1		
# participants affected / at risk	1/82 (1.22%)	1/79 (1.27%)
Diabetic neuropathy † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Dizziness † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Paraesthesia † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Syncope † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Respiratory, thoracic and mediastinal disorders		
Dyspnoea † 1		
# participants affected / at risk	2/82 (2.44%)	0/79 (0.00%)
Pleural effusion † 1		
# participants affected / at risk	2/82 (2.44%)	0/79 (0.00%)
Acute pulmonary oedema † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Pneumonitis † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)

Respiratory failure † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Skin and subcutaneous tissue disorders		
Skin discoloration † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Vascular disorders		
Hypotension † 1		
# participants affected / at risk	2/82 (2.44%)	0/79 (0.00%)
Deep vein thrombosis † 1		
# participants affected / at risk	0/82 (0.00%)	1/79 (1.27%)
Hypertension † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Orthostatic hypotension † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)
Venous thrombosis † 1		
# participants affected / at risk	1/82 (1.22%)	0/79 (0.00%)

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	Number at risk is based on the safety population defined as patients who were randomized and received at least one dose of study drug. A total of 164 participants were randomized and 3 participants did not receive study treatment (2 in the VR-CAP arm, 1 in the R-CHOP arm) for a total of 161 treated (82 in the VR-CAP arm, 79 in the R-CHOP arm).

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
VR-CAP	VELCADE, Rituximab, Cyclophosphamide, Doxorubicin and Prednisone
R-CHOP	Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone

Other Adverse Events

	VR-CAP	R-CHOP
Total, other (not including serious) adverse events		
# participants affected / at risk	73/82 (89.02%)	72/79 (91.14%)
Blood and lymphatic system disorders		
Anaemia † 1		

# participants affected / at risk	19/82 (23.17%)	17/79 (21.52%)
Eye disorders		
Conjunctivitis † 1		
# participants affected / at risk	5/82 (6.10%)	1/79 (1.27%)
Gastrointestinal disorders		
Constipation † 1		
# participants affected / at risk	24/82 (29.27%)	25/79 (31.65%)
Dyspepsia † 1		
# participants affected / at risk	11/82 (13.41%)	7/79 (8.86%)
Stomatitis † 1		
# participants affected / at risk	9/82 (10.98%)	7/79 (8.86%)
Abdominal pain upper † 1		
# participants affected / at risk	9/82 (10.98%)	4/79 (5.06%)
General disorders		
Fatigue † 1		
# participants affected / at risk	21/82 (25.61%)	11/79 (13.92%)
Oedema peripheral † 1		
# participants affected / at risk	14/82 (17.07%)	5/79 (6.33%)
Chills † 1		
# participants affected / at risk	2/82 (2.44%)	5/79 (6.33%)
Hepatobiliary disorders		
Hepatic function abnormal † 1		
# participants affected / at risk	8/82 (9.76%)	9/79 (11.39%)
Infections and infestations		
Nasopharyngitis † 1		
# participants affected / at risk	6/82 (7.32%)	3/79 (3.80%)
Investigations		
Weight decreased † 1		
# participants affected / at risk	6/82 (7.32%)	4/79 (5.06%)
Metabolism and nutrition disorders		
Decreased appetite † 1		
# participants affected / at risk	13/82 (15.85%)	5/79 (6.33%)
Hyperglycaemia † 1		
# participants affected / at risk	6/82 (7.32%)	2/79 (2.53%)
Hypophosphataemia † 1		
# participants affected / at risk	0/82 (0.00%)	4/79 (5.06%)
Musculoskeletal and connective tissue disorders		
Back pain † 1		
# participants affected / at risk	11/82 (13.41%)	6/79 (7.59%)
Arthralgia † 1		
# participants affected / at risk	7/82 (8.54%)	2/79 (2.53%)

Bone pain † 1		
# participants affected / at risk	**3/82 (3.66%)**	**6/79 (7.59%)**
Pain in extremity † 1		
# participants affected / at risk	**5/82 (6.10%)**	**3/79 (3.80%)**
Nervous system disorders		
Peripheral sensory neuropathy † 1		
# participants affected / at risk	**23/82 (28.05%)**	**15/79 (18.99%)**
Headache † 1		
# participants affected / at risk	**9/82 (10.98%)**	**8/79 (10.13%)**
Hypoaesthesia † 1		
# participants affected / at risk	**8/82 (9.76%)**	**4/79 (5.06%)**
Neuralgia † 1		
# participants affected / at risk	**9/82 (10.98%)**	**0/79 (0.00%)**
Dysgeusia † 1		
# participants affected / at risk	**5/82 (6.10%)**	**1/79 (1.27%)**
Psychiatric disorders		
Insomnia † 1		
# participants affected / at risk	**10/82 (12.20%)**	**6/79 (7.59%)**
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	**14/82 (17.07%)**	**11/79 (13.92%)**
Oropharyngeal pain † 1		
# participants affected / at risk	**6/82 (7.32%)**	**5/79 (6.33%)**
Skin and subcutaneous tissue disorders		
Alopecia † 1		
# participants affected / at risk	**10/82 (12.20%)**	**4/79 (5.06%)**
Pruritis † 1		
# participants affected / at risk	**6/82 (7.32%)**	**1/79 (1.27%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MeDRA Version 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 **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):

Offner F, Samoilova O, Osmanov E, Eom HS, Topp MS, Raposo J, Pavlov V, Ricci D, Chaturvedi S, Zhu E, van de Velde H, Enny C, Rizo A, Ferhanoglu B. Frontline rituximab, cyclophosphamide, doxorubicin, and prednisone with bortezomib (VR-CAP) or vincristine (R-CHOP) for non-GCB DLBCL. Blood. 2015 Oct 15;126(16):1893-901. doi: 10.1182/blood-2015-03-632430. Epub 2015 Jul 31.

Responsible Party:	Millennium Pharmaceuticals, Inc.
ClinicalTrials.gov Identifier:	NCT01040871 History of Changes
Obsolete Identifiers:	NCT01826084
Other Study ID Numbers:	**26866138-LYM-2034**
Study First Received:	December 29, 2009
Results First Received:	July 5, 2013
Last Updated:	December 11, 2013
Health Authority:	United States: Food and Drug Administration

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