# A Study of Nivolumab Plus Brentuximab Vedotin in Patients Between 5 and 30 Years Old, With Hodgkin's Lymphoma (cHL), Relapsed or Refractory From First Line Treatment

| CLINICALTRIALS.GOV IDENTIFIER | RECRUITMENT STATUS | FIRST POSTED | LAST UPDATE POSTED |
|---|---|---|---|
| NCT02927769 | ACTIVE, NOT RECRUITING | OCTOBER 7, 2016 | SEPTEMBER 1, 2022 |

## STUDY DESCRIPTION

### Brief Summary

The purpose of this study is to determine whether nivolumab plus brentuximab vedotin (followed by brentuximab vedotin plus bendamustine in patient with suboptimal response) is safe and effective in treating patients with Hodgkin's lymphoma (cHL). Eligible patients are children, adolescents, and young adults relapsed or refractory to first line.

**Condition or Disease:** Hodgkin Disease

**Intervention/treatment:** Biological: Nivolumab
Biological: brentuximab vedotin
Biological: bendamustine

**Phase:** Phase 2

## DETAILED DESCRIPTION

N/A

## STUDY DESIGN

**Study Type:** Interventional

**Estimated Enrollment :** 72 participants

**Allocation :** Non-Randomized

**Intervention Model :** Parallel Assignment

**Masking:** None (Open Label) ()

**Primary Purpose:** Treatment

**Official Title:** A Study of Nivolumab Plus Brentuximab Vedotin in Patients Between 5 and 30 Years Old, With Hodgkin's Lymphoma (cHL), Relapsed or Refractory From First Line Treatment

**Actual Study Start Date:** March 2017

**Estimated Primary Completion Date:** January 2024

**Estimated Study Completion Date:** November 2024

## ARMS AND INTERVENTIONS

| Arm | Intervention/treatment |
|---|---|
| Experimental: Nivolumab + brentuximab vedotin | Biological: Nivolumab<br>Specified Dose on Specified Days<br><br>Biological: brentuximab vedotin<br>Specified Dose on Specified Days |
| Experimental: brentuximab vedotin + bendamustine | Biological: brentuximab vedotin<br>Specified Dose on Specified Days<br><br>Biological: bendamustine<br>Specified Dose on Specified Days |

## OUTCOME MEASURES

Primary Outcome Measures:
1. Event Free Survival (EFS) [ Time Frame: Up to 5 years ]
Low Risk Group. Based on blinded independent central review (BICR)
2. Complete Metabolic Response (CMR) rate prior to HDCT/ASCT [ Time Frame: Up to 5 years ]
Standard Risk Group. This is the rate prior to high-dose chemotherapy followed by autologous stem cell transplant (HDCT/ASCT) based on the blinded independent central review (BICR) using Lugano 2014 criteria.
3. Complete Metabolic Response (CMR) rate at any time prior to radiation therapy [ Time Frame: Up to 5 years ]
Low Risk Group. The CMR rate is defined as the proportion of all response-evaluable participants who, assessed by the BICR, achieve best response of CMR using Lugano 2014 criteria.

Secondary Outcome Measures:
1. Overall Response Rate (ORR) after 4 cycles of nivolumab + brentuximab vedotin treatment [ Time Frame: Up to 12 weeks ]
Based on blinded independent central review (BICR)
2. Progression Free Survival Rate (PFSR) [ Time Frame: Up to 5 years ]
Based on the blinded independent central review (BICR)
3. Duration of Response (DOR) [ Time Frame: Up to 5 years ]
Based on the blinded independent central review (BICR)
4. Incidence of serious and non-serious adverse events of nivolumab (BMS-936558) and brentuximab when given in combination. [ Time Frame: Up to 5 years ]
measured by number of patients

5. Incidence of clinically significant abnormalities in general laboratory tests of nivolumab (BMS-936558) and brentuximab when given in combination. [ Time Frame: Up to 5 years ]
Hematology, Chemistry and Urinalysis
6. Incidence of clinically significant vital sign measurements of nivolumab (BMS-936558) and brentuximab when given in combination. [ Time Frame: Up to 5 years ]
Temperature, Blood Pressure and Heart Rate
7. Complete Metabolic Response (CMR) rate prior to HDCT/ASCT [ Time Frame: Up to 5 years ]
Standard Risk Group. This is the rate prior to high-dose chemotherapy followed by autologous stem cell transplant (HDCT/ASCT) based on investigator assessments using Lugano 2014 criteria.
8. Complete Metabolic Response (CMR) rate at any time prior to radiation therapy [ Time Frame: Up to 5 years ]
Low Risk Group. This is the rate prior to radiation therapy based on investigator assessments using Lugano 2014 criteria.
9. Event Free Survival (EFS) [ Time Frame: Up to 5 years ]
Low Risk Group. Based on investigator assessments
10. Overall Response Rate (ORR) after 4 cycles of nivolumab + brentuximab vedotin treatment [ Time Frame: Up to 12 weeks ]
Both Risk Groups. Based on investigator assessments
11. Progression Free Survival Rate (PFSR) [ Time Frame: Up to 5 years ]
Both Risk Groups. Based on investigator assessments
12. Duration of Response (DOR) [ Time Frame: Up to 5 years ]
Both Risk Groups. Based on investigator assessments

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**ELIGIBILITY CRITERIA**

**Ages Eligible for Study:** 5 to 30 Years (Child, Adult)

**Sexes Eligible for Study:** All

**Accepts Healthy Volunteers:** No

**Criteria**

Inclusion Criteria:
Classic Hodgkin Lymphoma (cHL), relapsed or refractory Minimal limitation on activities of daily living as measured by Karnofsky ≥ 50 for participants > 16 years of age or Lansky ≥ 50 for participants ≤ 16 years of age. One prior anti-cancer therapy that did not work
Exclusion Criteria:
Active, known, or suspected autoimmune disease or infection Active cerebral/meningeal disease related to the underlying malignancy More than one line of anti-cancer therapy or no treatment at all Received a stem cell transplant for Hodgkin Lymphoma and/or a solid organ transplant Prior treatment with any drug that targets T cell co-stimulation pathways (such as checkpoint inhibitors)
Other protocol defined inclusion/exclusion criteria apply

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**CONTACTS AND LOCATIONS**

**Contacts**

**Locations**

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|---|---|---|
| United States, Alabama | Children's Hospital of Alabama | Birmingham |
| United States, Arizona | Phoenix Children'S Hospital | Phoenix |
| United States, California | Loma Linda University Cancer Center | Loma Linda |
| United States, California | Valley Children's Hospital | Madera |
| United States, California | Children'S Hospital & Research Center At Oakland | Oakland |
| United States, California | Children'S Hospital Of Orange County | Orange |
| United States, California | Lucile Packard Children'S Research Hospital/Stanford Univ | Palo Alto |
| United States, California | Local Institution - 0091 | San Diego |
| United States, Colorado | Childrens Hospital of Colorado | Aurora |
| United States, Connecticut | Smilow Cancer Hospital At Yale New Haven Hospital | New Haven |
| United States, Delaware | Nemours / A. I. duPont Hospital for Children | Wilmington |
| United States, District of Columbia | Children'S National Medical Center | Washington |
| United States, Florida | Nemours Children'S Clinic | Jacksonville |
| United States, Florida | Local Institution - 0069 | Saint Petersburg |
| United States, Georgia | Children's Healthcare Of Atlanta | Atlanta |
| United States, Iowa | University Of Iowa | Iowa City |
| United States, Maryland | John Hopkins University | Baltimore |
| United States, Massachusetts | Dana Farber Cancer Institute. | Boston |
| United States, Mississippi | University Of Mississippi Medical Center | Jackson |
| United States, Missouri | Children'S Mercy Hospital And Clinics | Kansas City |

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|---|---|---|
| United States, Missouri | Washington University School Of Medicine | Saint Louis |
| United States, Nevada | Nevada Cancer Research Foundation | Las Vegas |
| United States, New Jersey | Hackensack University Medical Center | Hackensack |
| United States, New Jersey | Rutgers Cancer Institute of New Jersey | New Brunswick |
| United States, New York | Roswell Park Cancer Institute | Buffalo |
| United States, North Carolina | Local Institution | Chapel Hill |
| United States, North Carolina | Carolinas Medical Center | Charlotte |
| United States, Ohio | Cincinnati Children'S Hospital Medical Center | Cincinnati |
| United States, Ohio | Nationwide Children'S Hospital | Columbus |
| United States, Oklahoma | University Of Oklahoma Health Sciences Center | Oklahoma City |
| United States, Pennsylvania | Penn State Milton S. Hershey Medical Center | Hershey |
| United States, Pennsylvania | Childrens Hospital Of Philadelphia | Philadelphia |
| United States, Pennsylvania | Childrens Hospital Of Pittsburgh Of Upmc | Pittsburgh |
| United States, Tennessee | Vanderbilt University | Nashville |
| United States, Texas | Dell Children'S Medical Center Of Central Texas | Austin |
| United States, Texas | Local Institution - 0071 | Dallas |
| United States, Texas | Baylor College Of Medicine | Houston |
| United States, Utah | Primary Children's Hospital | Salt Lake City |
| United States, Virginia | Children'S Hosp-Kings Daughter | Norfolk |
| United States, Virginia | Virginia Commonwealth University | Richmond |
| United States, Washington | Seattle Childrens Hospital | Seattle |
| United States, Wisconsin | Children'S Hospital Of Wisconsin | Milwaukee |
| Canada, Alberta | Local Institution | Calgary |
| Canada, Ontario | Local Institution | Toronto |
| Canada, Quebec | The Montreal Children's Hospital of the MUHC | Montreal |
| Czechia | Klinika detske hematologie a onkologie | Praha 5 |
| France | Hôpital Jeanne de Flandre | Lille |
| France | CHU Lyon GH Est | Lyon Cedex 08 |
| France | Hopital De La Timone | Marseille Cedex 5 |
| France | Local Institution | Nantes |
| France | Hopital Enfants Armand Trousseau | Paris |
| France | Hopital Robert Debre | Paris |
| France | CHU de Toulouse - Hopital des Enfants | Toulouse cedex 9 |
| France | CHRU Nancy - Hopital Brabois Enfant | Vandoeuvre les Nancy |
| France | Institut Gustave Roussy | Villejuif Cedex |
| Germany | Local Institution - 0056 | Berlin |
| Germany | Uniklinikum Giessen und Marburg | Giessen |
| Germany | Mhh Kinderklinik | Hannover |
| Germany | Local Institution - 0102 | Muenchen |
| Ireland | Local Institution | Dublin |
| Italy | Cro-Aviano | Aviano (PN) |
| Italy | Local Institution - 0020 | Bologna |
| Italy | Irccs Istituto G. Gaslini | Genova |
| Italy | Local Institution - 0019 | Monza (mb) |
| Italy | Ao Santobono - Pausilipon | Napoli |

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|---|---|---|
| Italy | AOU Policlinico Umberto I | Roma |
| Netherlands | Local Institution | Rotterdam |
| Netherlands | Local Institution | Utrecht |
| Poland | Local Institution | Gdansk |
| Poland | Local Institution | Krakow |
| Spain | Local Institution - 0082 | Barcelona |
| Spain | Local Institution | Madrid |
| United Kingdom, Greater London | Local Institution | London |
| United Kingdom, North Yorkshire | Local Institution | Leeds |
| United Kingdom, Yorkshire | Local Institution | Leeds |
| United Kingdom | Local Institution | Birmingham |
| United Kingdom | Local Institution | Glasgow |
| United Kingdom | Local Institution | Manchester |

**Sponsors and Collaborators**

Bristol-Myers Squibb

Seagen Inc.

**Investigator**

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|---|---|---|
| Study Director : | Bristol-Myers Squibb | Bristol-Myers Squibb |

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**MORE INFORMATION**

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| **Responsible Party :** | Bristol-Myers Squibb |
| **ClinicalTrials.gov Identifier :** | NCT02927769 |
| **Other Study ID Numbers :** | CA209-744, 2016-002347-41 |
| **First Posted :** | October 7, 2016 |
| **Last Update Posted :** | September 1, 2022 |
| **Last Verified :** | August 2022 |
| **Studies a U.S. FDA-regulated Drug Product:** | Yes |
| **Studies a U.S. FDA-regulated Device Product:** | No |
| **Additional relevant MeSH terms :** | *Hodgkin Disease*<br>*Lymphoma*<br>*Neoplasms by Histologic Type*<br>*Neoplasms*<br>*Lymphoproliferative Disorders*<br>*Lymphatic Diseases*<br>*Immunoproliferative Disorders*<br>*Immune System Diseases* |