CLINICAL TRIAL RESULTS

Researchers look at the results of many studies to decide which treatments may offer patients improvements in terms of efficacy and safety. It takes people taking part in many studies around the world to help researchers decide this. This summary only shows the results from this study. Other studies might have different results.

Sponsor	**BeiGene, Ltd.**
Medicine(s) Studied	**Tislelizumab**
Protocol Number	**BGB-A317-210**
Dates of Study	**August 2020 to August 2024**
Title of This Study	**A Phase 2, Multicenter, Open-Label Study of Tislelizumab (BGB-A317) in Patients With Relapsed or Refractory Classical Hodgkin Lymphoma**
Date of This Report	**August 2025**

Thank You!

BeiGene, the sponsor of this study, thanks all patients for taking part in the clinical trial evaluating a new medical treatment called tislelizumab (also known as BGB-A317). Through this study, researchers gained valuable insights into the safety and efficacy of this treatment combination and how it may benefit patients with a type of cancer called Classical Hodgkin Lymphoma (cHL).

BeiGene thinks it is important to share the results of the study with the public. If you participated in the study and have questions about the results, please speak with the doctor or staff at your study center.

Why was this study done?

Researchers are looking for better ways to help people with different types of cancer, including cHL. cHL is a type of lymphoma which is a cancer that starts in the lymphatic system, which is part of the body's immune defense. It is characterized by the presence of abnormal cells not found on other lymphomas. In its early stages, cHL may cause painless swelling of the lymph nodes, most commonly in the neck, underarms, or groin. As the disease advances, symptoms may include persistent fatigue, fever, night sweats, unexplained weight loss, or itching. While cHL is often considered one of the more treatable forms of cancer, especially when detected early, advanced or relapsed cases may require more aggressive and personalized treatment.

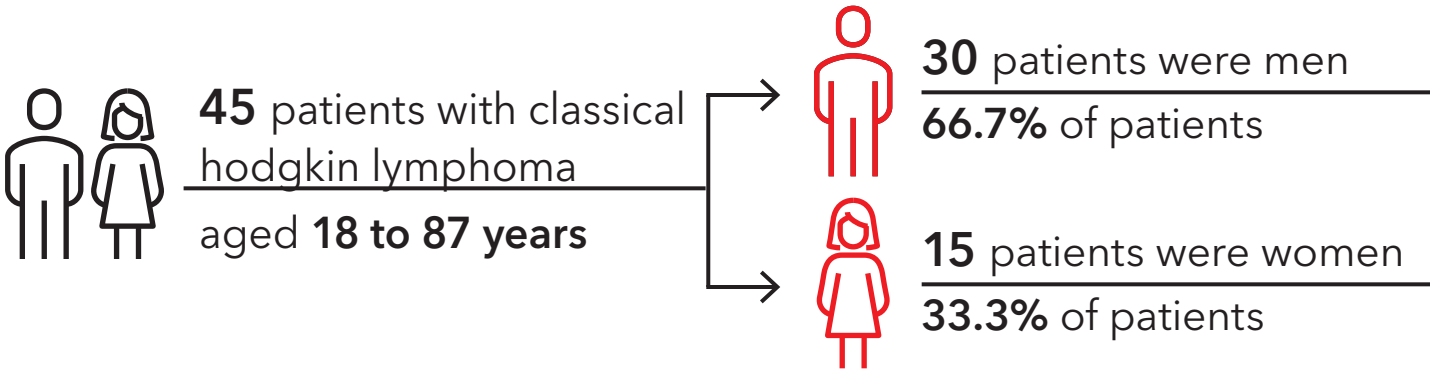
In this study, researchers aimed to better understand how safe and effective tislelizumab is in people with relapsed or refractory cHL. Tislelizumab is a protein that binds to an immune checkpoint called programmed cell death protein 1 (PD-1). By blocking PD-1, tislelizumab helps to restore the ability of T-cells to detect and attack cancer cells, allowing the immune system to respond more effectively. In this trial, participants with cHL which had progressed after stem cell transplantation or who were not candidates for transplant received tislelizumab intravenously every three weeks. This study may help support a more personalized approach to treating relapsed or refractory cHL.

Researchers in this study wanted to know:

- What adverse events would patients who took part in this study have?
- How many patients who took part in the study would no longer have evidence of cancer or have some improvement in the signs and symptoms of cancer?

Who was in this study?

A total of 46 patients between the ages of 18 and 87 years were in the study. Out of the 46 patients, 45 received treatment. There were 30 men (66.7%) and 15 women (33.3%).



When and where was this study done?

This study started in August 2020 and finished in August 2024. The study was done at 20 study centers in 4 countries, including:

- Australia, with 2 patients
- France, with 38 patients
- United States, with 3 patients
- Belgium, with 3 patients

How was this study done?

In this study, researchers tested how safe and effective tislelizumab was for people with relapsed or refractory cHL. Patients were grouped based on their prior treatments. Some had disease that returned or did not respond after a stem cell transplant, while others had previously received at least one treatment and were not eligible for a transplant. The main goal was to see how many people had their cancer shrink or disappear during treatment.

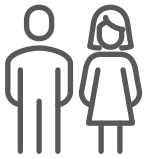
People in Cohort 1 included patients whose disease did not respond or worsened after an autologous hematopoietic stem cell transplant (a procedure using their own stem cells). Cohort 2 included patients whose disease worsened after at least one prior systemic therapy and who were not eligible for either autologous (their own stem cells) or allogeneic (donor stem cells) stem cell transplantation. All patients in both cohorts received 200 milligrams of tislelizumab (also known as BGB-A317) through an intravenous (IV) infusion every three weeks. Treatment continued until the cancer worsened, side effects became too difficult to manage, a different treatment was needed, the patient or their doctor decided to stop, a new medication that could not be taken with the study drug was needed, the patient chose to leave the study.

15 patients
were assigned to
Cohort 1 treatment group

14 patients
were infused with
tislelizumab intravenously

200 mg

EVERY 3 WEEKS



31 patients
were assigned to
Cohort 2 treatment group

31 patients
were infused with
tislelizumab intravenously

200 mg

EVERY 3 WEEKS

During the study, the trial doctors:

- Checked patients' overall health and took blood and urine samples
- Asked patients how they were feeling and what medicines they were taking
- Asked patients how well they could move and do their daily activities
- Measured how well patients' hearts were using an electrocardiogram machine
- Took images of patients' bodies with a machine to determine the status of their cancer

What adverse events did patients have?

Adverse events are medical problems that may or may not be caused by the study treatment. An adverse event is called "serious" if it causes long-lasting problems, puts the patient in the hospital, is life-threatening, is considered medically important by the study researcher, or leads to death. A total of 45 treated patients were evaluated for adverse events in this study.

Below are the adverse events that patients had in this study. The websites listed at the end of this summary may have more information about the adverse events that occurred in this study.

In this study:

- 93.3% of patients had at least 1 adverse event
- 28.9% of patients had at least one serious adverse event
- 6.7% of patients had adverse events that caused them to stop the treatment permanently.

What serious adverse events did patients have?

Each serious adverse event occurred in only one patient.

Serious adverse event	Cohort 1 (Out of 14 patients)	Cohort 2 (Out of 31 patients)
Blood creatine phosphokinase increased	7.1% (1 Patient)	0.0% (0 Patients)
Lipase increased	7.1% (1 Patient)	0.0% (0 Patients)
Aspartate aminotransferase increased	0.0% (0 Patients)	3.2% (1 Patient)
Alanine aminotransferase increased	0.0% (0 Patients)	3.2% (1 Patient)
Troponin increased	0.0% (0 Patients)	3.2% (1 Patient)
Chest pain	0.0% (0 Patients)	3.2% (1 Patient)
Pyrexia (fever)	0.0% (0 Patients)	3.2% (1 Patient)
Peritonitis (infection in the belly)	0.0% (0 Patients)	3.2% (1 Patient)
Sepsis (infection of the blood)	0.0% (0 Patients)	3.2% (1 Patient)
Infusion related reaction	0.0% (0 Patients)	3.2% (1 Patient)
Tendon rupture	0.0% (0 Patients)	3.2% (1 Patient)
Musculoskeletal chest pain	7.1% (1 Patient)	0.0% (0 Patients)
Polyarthritis (swelling in the joints)	0.0% (0 Patients)	3.2% (1 Patient)
Coeliac disease (reaction to gluten)	0.0% (0 Patients)	3.2% (1 Patient)
Cutaneous T-cell lymphoma	7.1% (1 Patient)	0.0% (0 Patients)
Dyspnoea (shortness of breath)	7.1% (1 Patient)	0.0% (0 Patients)
Skin ulcer	0.0% (0 Patients)	3.2% (1 Patient)

Only one patient (2.2%) had an adverse event of peritonitis (infection in the belly), unrelated to study treatment, that led to death.

What were the most common adverse events?

Asthenia, which means unusual weakness or lack of energy, was the most common adverse event. The most common side effects (adverse events) that occurred in at least 20% of the patients in each cohort of this study are shown here

Adverse event	Cohort 1 (Out of 14 patients)	Cohort 2 (Out of 31 patients)
Asthenia (feeling abnormally weak or tired)	7.1% (1 patient)	29.0% (9 patients)
Dry skin	21.4% (3 patients)	6.5% (2 patients)
Cough	21.4% (3 patients)	16.1% (5 patients)
Shortness of breath	21.4% (3 patients)	9.7% (3 patients)

What were the main results of the study?

Below is a summary of the main results of this study. The results for each patient in the study are not shown here and may be different from the overall results shown below.

You can find a full list of the questions for this study on the websites listed on the last page of this summary. If results are already available, they will also be found on these websites.

How many patients who took part in this study no longer had evidence of cancer or had some improvement in the signs and symptoms of cancer?

Measuring **overall response rate** is one way to determine how well a new cancer treatment works, that is, how many patients had their cancer shrink or go away. In this study, doctors followed up with patients for a median of 11.4 months which means half of the patients were followed for less than 11.4 months, and the other half were followed for more than 11.4 months. After this time, 64.3% of patients in Cohort 1 and 64.5% of patients in Cohort 2 who received tislelizumab showed improvement based on imaging of their cancer.

How has this study helped patients and researchers?

The results from this study will help researchers understand more about how tislelizumab works in patients with cHL.

The results in this summary come from this one study. Other studies may show different results. If you participated in this study and have questions about the results, please speak to the doctor or staff at your study center. You should not make changes to your treatments based on the results of this study.

Where can I found out more about this study?

More information about this study, including any available results, is found below:

The full title of this study is

A Phase 2, Multicenter, Open-Label Study of Tislelizumab (BGB-A317) in Patients With Relapsed or Refractory Classical Hodgkin Lymphoma

The protocol number is

BGB-A317-210

For information about this study in the United States

Click here

For information about this study in the European Union

Click here

For information about this study from BeiGene

Click here

Clinical study participants help researchers make important discoveries that may lead to new medical treatments worldwide. BeiGene sponsored this study and is thankful for the help of the patients in this study.

For more information about BeiGene:

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BeiGene thanks all the participants for their time and effort that went into making this study possible. Clinical study patients help advance science!