CLINICAL TRIAL RESULTS

Researchers look at the results of many studies to decide which treatments may be best and safest for patients. It takes people taking part in many studies around the world to help researchers make these decisions. This summary only shows the results from this study. Other studies might have different results.

Sponsor	BeiGene, Ltd.
Medicine(s) Studied	Tislelizumab (BGB-A317)
Protocol Number	BGB-A317-309
Dates of Study	March 2019 to December 2023
Title of This Study	Tislelizumab Combined with Chemotherapy Versus Chemotherapy Alone in Recurrent or Metastatic Nasopharyngeal Cancer
Date of This Report	October 2024

Thank You!

BeiGene, who managed this study, thanks participants for taking part in the clinical study for a new medical treatment called tislelizumab. In this study, researchers learned more about the safety and efficacy of tislelizumab, also called BGB-A317, and how it may work in patients with a type of cancer called Nasopharyngeal Cancer (NPC).

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 nasopharyngeal cancer. NPC begins in the nasopharynx, the upper part of the throat behind the nose. It is a highly aggressive cancer driven by genetic changes that cause the cells in this area to grow uncontrollably. In its early stages, nasopharyngeal cancer often shows no symptoms, making early detection challenging. As it progresses, individuals may experience nasal congestion, nosebleeds, hearing loss, or neck lumps. In advanced cases, the cancer can block airways or affect nearby structures, requiring quick medical care and special treatments.

In this study, researchers wanted to learn how safe and helpful tislelizumab is for patients with NPC when combined with the chemotherapy drugs gemcitabine and cisplatin compared to using chemotherapy alone. Tislelizumab helps the immune system fight cancer by blocking PD-1, which stands for Programmed Cell Death Protein 1. PD-1 is a protein on immune cells that acts as a brake, preventing them from attacking nearby cells. This is important for protecting healthy cells, but cancer cells can use PD-1 to hide from the immune system. By blocking PD-1, tislelizumab helps immune cells recognize and attack cancer cells. Cisplatin and gemcitabine are commonly used together and are known to be effective and well-tolerated as a first treatment for NPC that has come back or spread.

Before a new medical treatment can be approved for people to take, researchers must do clinical studies to learn how safe the treatment is by looking at adverse events, or side effects. Adverse events are unwanted medical problems that study participants can experience that may or may not be caused by the study drug. Researchers also must learn how the treatment works in people with the disease.

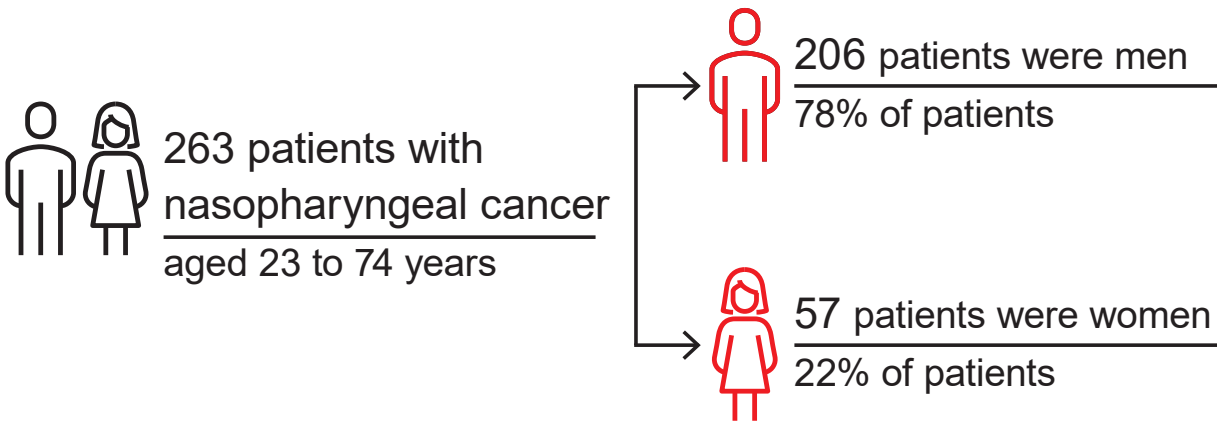
In this study, researchers compared tislelizumab to the standard chemotherapy treatment used for NPC.

Researchers in this study wanted to know:

- What adverse events would patients who took part in this study have?
- How long did patients participating in the study live without their cancer getting worse ?
- How long did patients participating in this study live after receiving this treatment?
- How many people who took part in the study no longer had evidence of cancer or had some improvement in the signs and symptoms of active disease?

Who was in this study?

A total of 263 patients between the ages of 23 and 74 years were in the study. There were 206 men (78.3%) and 57 women (21.7%). All patients had a confirmed diagnosis of NPC and had not received any treatment for recurrent or metastatic NPC before. The patients did not have other medical conditions that could affect the study results.



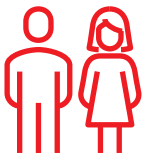
When and where was this study done?

This study started in March 2019 and ended in December 2023. The study was done at 37 study centers in 3 countries, including:

- Mainland China, with 248 patients
- Taiwan, with 9 patients
- Thailand, with 6 patients

How was this study done?

In this study, patients with NPC were randomly put into one of two groups: one group received tislelizumab along with gemcitabine and cisplatin, while the other group received a placebo (a fake treatment) along with gemcitabine and cisplatin. The patients in the tislelizumab group got 200 milligrams of tislelizumab through an IV once every 3 weeks, along with the standard doses of gemcitabine and cisplatin. The placebo group got an injection that looked like tislelizumab but had no active ingredients, plus the standard doses of the other drugs. Randomly assigning patients to these groups helps ensure the groups are as similar as possible, so researchers can fairly compare the results.

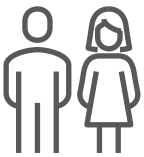


131 patients
were assigned to the
tislelizumab + gemcitabine + cisplatin
treatment group

Patients were infused with
tislelizumab

EVERY 3 WEEKS

+ gemcitabine + cisplatin infusion



132 patients
were assigned to the
placebo + gemcitabine + cisplatin
treatment group

Patients were infused with
placebo

EVERY 3 WEEKS

+ gemcitabine + cisplatin infusion

During this study, study 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 an X-ray machine to determine the tumor's status
- Collected samples of fresh tumor tissue from patients.

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 263 patients received at least one dose of study drug and were assessed for adverse events.

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.

- 100% of patients in the tislelizumab group and 99.2% of patients in the placebo group had at least 1 adverse event
- 35.3% of patients in the tislelizumab group and 35.4% of the patients in the placebo group had serious adverse events
- 16.5% of patients in the tislelizumab group and 10.8% of the patients in the placebo group had adverse events that caused them to stop the treatment.

What serious adverse events did patients have?

A drop in platelet count, which is when the number of tiny cells in the blood that help stop bleeding is lower than normal, was the most common serious side effect in this study, affecting at least 2% of patients.

Most common serious adverse events		
Serious adverse event	Tislelizumab (133 Patients)	Placebo (130 Patients)
Platelet count decreased	6.8% (9 patients)	10.8% (14 patients)
Sepsis	3.0% (4 patients)	0
Thrombocytopenia	3.0% (4 patients)	2.3% (3 patients)
Anaemia	2.3% (3 patients)	3.8% (5 patients)
Neutrophil count decreased	2.3% (3 patients)	4.6% (6 patients)
White blood cell count decreased	2.3% (3 patients)	3.8% (5 patients)

A total of 6 patients (4.5%) in the tislelizumab group and 2 (1.5%) in the placebo group had adverse events that led to death. Two (1.5%) of the adverse events leading to death in the tislelizumab group and 2 (1.5%) in the placebo group were possibly related to the study treatments.

What were the most common adverse events?

Anemia was the most common adverse event in both groups. The table below shows the most common adverse events that occurred in at least 50% of the patients in this study.

Most common adverse events		
Adverse event	Tislelizumab (133 Patients)	Placebo (130 Patients)
Anaemia	87.2% (116 patients)	90.8% (118 patients)
White blood cell count decreased	61.7% (82 patients)	63.1% (82 patients)
Neutrophil count decreased	61.7% (82 patients)	59.2% (77 patients)
Nausea	58.6% (78 patients)	72.3% (94 patients)
Platelet count decreased	54.1% (72 patients)	61.5% (80 patients)
Decreased appetite	48.1% (64 patients)	50.0% (65 patients)
Vomiting	41.4% (55 patients)	53.1% (69 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 long do patients live without their cancer getting worse?

Researchers wanted to know how long patients survived without NPC getting worse after starting study treatment, also known as progression free survival. After 4.4 years of follow-up, patients on tislelizumab plus chemotherapy had a 47% lower chance of their cancer growing or spreading compared with patients receiving placebo plus chemotherapy. During this time, the median length of time that patients survived without NPC getting worse was 9.6 months in the tislelizumab group and 7.4 months for patients in the placebo group. Median is the middle number in a group of numbers.

How long did patients participating in this study live after receiving treatment?

Measuring overall survival is one way to determine how well a new cancer treatment works. Overall survival is the median amount of time that patients live after the start of treatment. In this study, some patients lived for a shorter time, and some lived longer. Patients in the tislelizumab group lived a median of about 45 months. Patients in the placebo group lived about 32 months. This means that patients in the tislelizumab group lived a median of 13.5 months longer compared to patients in the placebo group. A total of 263 patients were included in this analysis.

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

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How has this study helped people and researchers?

The results from this study will help researchers understand more about how tislelizumab works in patients with NPC and may provide additional treatment options for patients in the future. More studies with tislelizumab are ongoing and planned.

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 find out more about this study?

More information about this study, including any available results, can be found on the websites below:

The full title of this study is

A Phase 3, Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Compare the Efficacy and Safety of Tislelizumab (BGB-A317) Combined With Gemcitabine Plus Cisplatin Versus Placebo Combined With Gemcitabine Plus Cisplatin as First-Line Treatment for Recurrent or Metastatic Nasopharyngeal Cancer

The protocol number is

BGB-A317-309

For information about this study in the United States

Click here

For information about this study from China

Click here

For information about this study from BeiGene

Click here

Clinical study patients 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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