CLINICAL TRIAL RESULTS

Researchers look at the results of many studies to decide if a study treatment works, how it works, and if it is safe 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-A317-302
Dates of Study	January 2018 to December 2022
Title of This Study	A Study of Tislelizumab (BGB-A317) Versus Chemotherapy as Second Line Treatment in Participants With Advanced Esophageal Squamous Cell Carcinoma
Date of This Report	September 2023

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 advanced esophageal squamous cell carcinoma.

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 advanced esophageal squamous cell carcinoma (ESCC). ESCC begins in the esophagus, the tube that carries food from the throat to the stomach. It is a very aggressive cancer caused by genetic changes that make esophageal cells grow uncontrollably. Early on, ESCC often shows no symptoms, which makes it hard to find. But as it gets worse, people may have trouble swallowing, lose weight without trying, and feel chest or throat discomfort. In severe cases, ESCC can block the esophagus and make breathing difficult, needing quick medical treatment and personalized therapies.

In this study, researchers wanted to learn more about how safe tislelizumab is and how it works in patients with ESCC who are not eligible for surgery. Tislelizumab is a protein that strongly binds to a cell surface protein called PD-1. By binding to PD-1, tislelizumab helps the body's natural immune cells (called T-cells) protect the body from infection and attack cancer cells.

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.

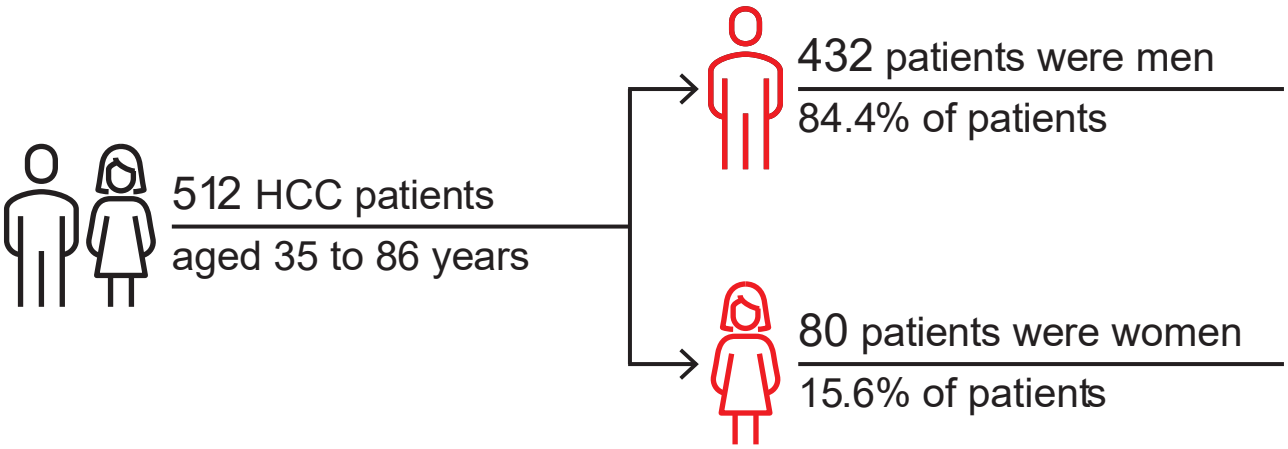
In this study, researchers compared tislelizumab to the standard chemotherapy treatment used for ESCC.

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 this study live after receiving this treatment?

Who was in this study?

A total of 512 patients between the ages of 35 and 86 years were in the study. There were 432 men (84.4%) and 80 women (15.6%). All patients had a confirmed diagnosis of ESCC and had tried only one other type of treatment, such as chemotherapy. The patients did not have other medical conditions that could affect the study results.



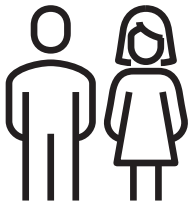
When and where was this study done?

This study started in January 2018 and ended in December 2022. The study was done at 132 study centers in 11 countries, including:

- Mainland China, with 296 patients
- Taiwan, with 27 patients
- South Korea, with 31 patients
- Japan, with 50 patients
- France, with 30 patients
- United Kingdom, with 18 patients
- Italy, with 10 patients
- Spain, with 24 patients
- Germany, with 10 patients
- Belgium, with 14 patients
- United States, with 2 patients

How was this study done?

In this study, patients with ESCC were randomly put into 1 of 2 treatment groups – either tislelizumab or the standard chemotherapy treatment (ICC). Patients in the tislelizumab group were given 200 milligrams (mg) of tislelizumab as an infusion through a vein once every 3 weeks. Patients in the ICC group received either paclitaxel, docetaxel, or irinotecan at standard doses. Putting patients into groups by chance helps to make the groups more equal. That way, researchers can understand the results between the groups in the most fair way.



All patients with ESCC were infused with tislelizumab

EVERY 3 WEEKS

During this study, the doctors:

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

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 495 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.

In this study:

- 96.1% of patients in the tislelizumab group and 98.3% of patients in the ICC group had at least 1 adverse event
- 42.7% of patients in the tislelizumab group and 44.2% of the patients in the ICC group had serious adverse events
- 19.2% of patients in the tislelizumab group and 26.7% of the patients in the ICC group had adverse events that caused them to stop the treatment.

What serious adverse events did patients have?

Pneumonia was the most common serious adverse event that occurred in at least 7.5% of patients in this study.

A total of 14 patients (5.5%) in the tislelizumab group and 14 (5.8%) in the ICC group had adverse events that led to death. Five (2.0%) of the adverse events leading to death in the tislelizumab group and 7 (2.9%) in the ICC 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 the following shows the most common adverse events that occurred in at least 20% of the patients in this study.

Adverse event	Tislelizumab (255 patients)	ICC (240 patients)
Anemia	31.4% (80 patients)	45.4% (109 patients)
Decreased Weight	24.3% (62 patients)	18.8% (45 patients)
Nausea	14.5% (37 patients)	30% (72 patients)
Vomiting	10.6% (27 patients)	20% (48 patients)
Neutrophil Count Decreased	2.4% (6 patients)	39.2% (94 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 there are results already available, they will also be found on these websites.

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

Measuring overall survival is one way to determine how well a new treatment works. Overall survival is the median amount of time that patients live after treatment. In this study, some patients lived for a shorter time, and some lived longer. Patients in the tislelizumab group lived about 8 and a half months. Patients in the ICC arm lived about 6 months. This means that patients in the tislelizumab group lived on average 2 months longer compared to patients in the ICC group. A total of 512 patients were included in this analysis.

How has this study helped people?

The results from this study will help researchers understand more about how tislelizumab works in patients with ESCC 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, is found below:

The full title of this study is

A Randomized, Controlled, Open-label, Global Phase 3 Study Comparing the Efficacy of the Anti-PD-1 Antibody Tislelizumab (BGB-A317) Versus Chemotherapy as Second Line Treatment in Patients With Advanced Unresectable/Metastatic Esophageal Squamous Cell Carcinoma

The protocol number is BGB-A317-302

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 in 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 study patients.

For more information about BeiGene:

- Our main office is located in San Mateo, CA, USA
- Our phone number is +1 (877) 828-5568
- Our email address is ClinicalTrials@beigene.com

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