

Summary of Clinical Trial Results

For Laypersons



A study to learn how effective and safe a medicine containing veliparib is compared to placebo (no medicine) taken in combination with standard chemotherapy to treat adult patients with certain types of advanced lung cancer

Overall Summary

- Researchers are looking for a better way to treat a certain type of lung cancer: advanced or metastatic squamous non-small cell lung cancer.
 - In this study, study doctors wanted to know whether patients with this type of lung cancer live longer when taking an experimental drug called veliparib, taken with the standard chemotherapy drugs carboplatin and paclitaxel compared to placebo (no medicine) taken with carboplatin and paclitaxel.
 - This study took place from April 2014 to November 2019 in 37 countries.
 - A total of 970 adults with advanced or metastatic squamous non-small cell lung cancer took part in this study. Most patients experienced natural disease progression or passed away.
 - The study was divided into 4 periods: the Screening Period, Treatment Period, Post-Treatment Period, and Survival Follow-Up.
- Patients took veliparib or placebo by mouth. Carboplatin and paclitaxel were given to patients by injection into their veins.
- Current smokers did not show significant improvement in overall survival when they received veliparib compared to patients who received placebo. Overall survival in all of the patients, no matter their smoking status, was 1 month longer among patients who received veliparib compared to patients who received placebo.
 - Side effects were the same as those expected in this patient population and similar to side effects seen with the chemotherapy drugs used in other studies.
 - The results of the study may be used by researchers to further develop this medicine.
 - If you participated in this study and have questions about your individual care, contact the doctor or staff at your study site.

1. General information about the study

1.1 What was the main objective of this study?



Researchers are looking for a better way to treat advanced and metastatic squamous non-small cell lung cancer using an experimental drug called veliparib. Non-small cell lung cancer is a form of lung cancer and accounts for more than 85% of all lung cancer cases.

- **Squamous** is a certain subtype of non-small cell lung cancer.
- **Advanced cancer** means it has spread to surrounding tissues.
- **Metastatic cancer** means it has spread to a different part of the body from where it started (in this case, from the lungs).

Doctors suggest chemotherapy (use of medicines to destroy cancer cells) as a standard of care to treat the types of lung cancer described above. Researchers in this study wanted to know whether veliparib, in combination with standard chemotherapy drugs carboplatin and paclitaxel, could help treat this type of lung cancer better than carboplatin and paclitaxel alone.

Veliparib stops certain proteins in the body that help cancer cells overcome damage caused by radiation and anti-cancer drugs. Veliparib blocks these proteins, preventing cancer cells from repairing themselves to help make cancer treatments more effective.

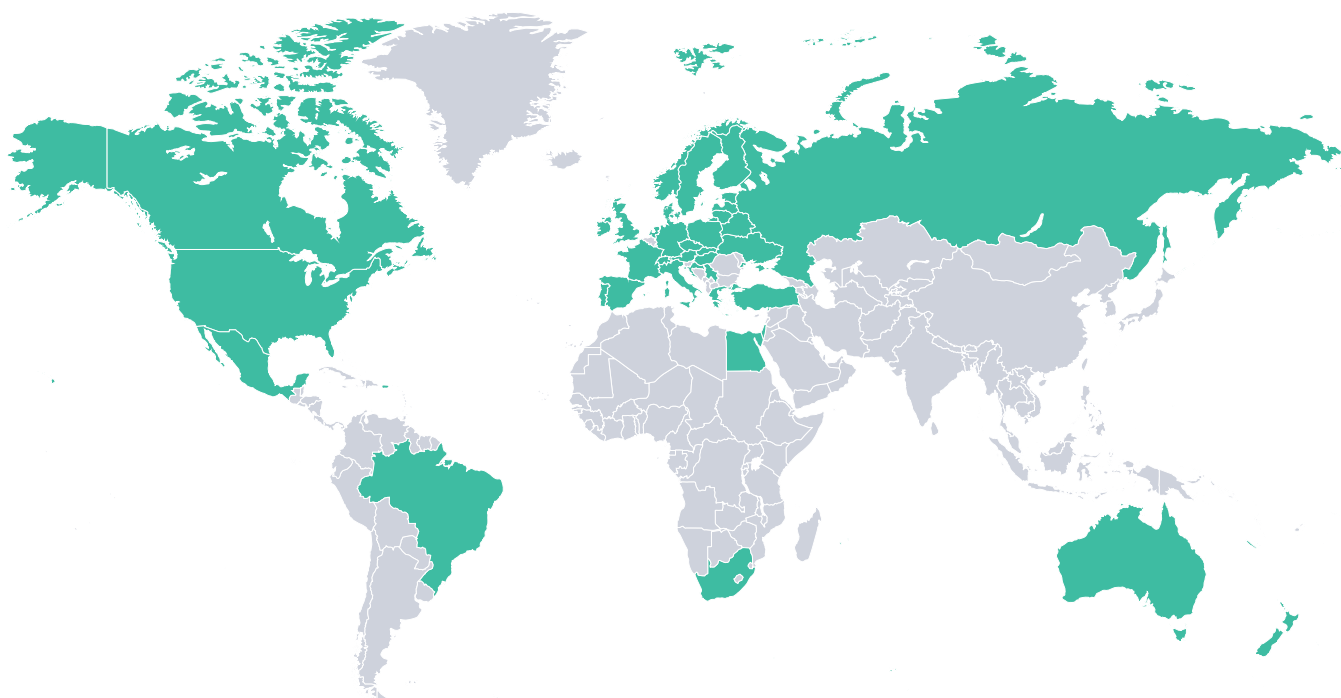
The doctors in this study treated adult patients who were diagnosed with advanced or metastatic squamous non-small cell lung cancer but were not previously treated with chemotherapy. Researchers planned this study as a Phase 3, double-blind, randomized study.

- **Phase 3 studies** test potential new treatments in a large number of patients with a condition or disease. In this Phase 3 study, the study doctors looked at the benefits of veliparib with chemotherapy versus placebo with chemotherapy in patients.
- A **placebo** is something that looks like the treatment being tested (in this case, a capsule that looks like veliparib) but contains no real medicine. Researchers used a placebo to compare the results for patients who took chemotherapy with veliparib with the results for patients who took chemotherapy without veliparib.
- This study was also **randomized and “double-blinded”**, which means that patients were randomly (by chance) assigned to treatment groups, and neither the patients nor the study doctors knew who was given veliparib or who was given placebo. This process ensures that no study results were influenced.

The main aim of the study was to find out whether the overall survival (how long patients lived) in patients who were current smokers improved after the addition of veliparib to carboplatin and paclitaxel compared to placebo taken with carboplatin and paclitaxel. The study also measured overall survival in all of the patients, no matter their smoking status. The study doctors also looked for any side effects patients may have had after treatment with the study drugs. This summary only includes the results of this study, which may be different from the results of other studies.

1.2. When and where was the study done?

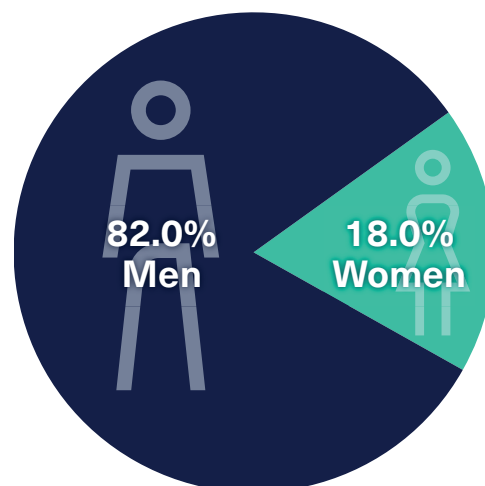
This study took place from April 2014 to November 2019 in Australia, Austria, Belarus, Brazil, Canada, Croatia, Czechia, Denmark, Egypt, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Israel, Italy, Latvia, Lithuania, Mexico, Netherlands, New Zealand, Norway, Poland, Portugal, Puerto Rico, Russian Federation, Serbia, Slovakia, South Africa, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom, and United States.



2. What patients were included in this study?

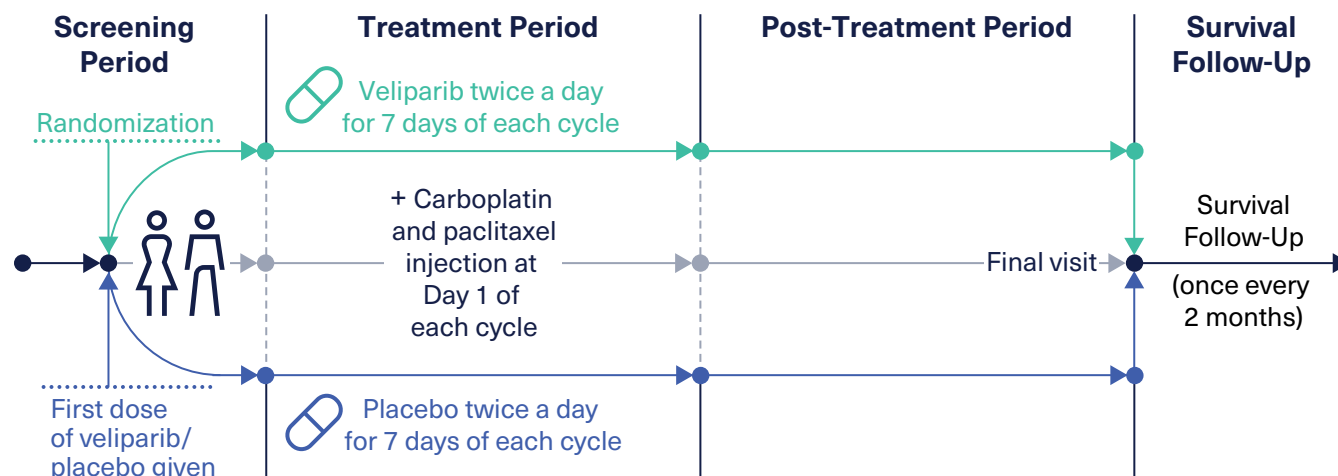
A total of 970 adult patients took part in the study. More men (82%) than women (18%) participated in the study. Patients ranged from 33 to 84 years of age, with an average age of 64. The majority of patients were current smokers (57%) or past smokers (37%), which is typical for this type of lung cancer. Study doctors selected only adults to participate in this study. Patients either had metastatic disease or locally advanced disease that was untreatable by surgery or radiation. Patients must not have had chemotherapy treatment for advanced non-small cell lung cancer before this study.

In 2019, it was estimated that only 1 in 5 patients in the United States will survive five years following the diagnosis of lung cancer. This study followed patients with cancer to see if treatment improved the length of survival time. This study also followed patients until they left the study or passed away. Most patients experienced natural disease progression or passed away. Over half of the study patients completed the scheduled treatment, and the remainder discontinued treatment early mostly due to disease progression or side effects.



3. Which medicines were studied?

The medicine in this study was veliparib, taken in combination with carboplatin and paclitaxel. The diagram below shows how the study was organized.



The study was divided into 4 periods:

- **Screening Period** – Before the study started, the Screening Period took place to check if patients could join the study. Once patients were screened, they were randomly (by chance) assigned to treatment groups (veliparib treatment or placebo treatment) without the patients or study doctors knowing who was given which treatment. Patients took capsules of veliparib or placebo by mouth.
- **Treatment Period** (each Cycle = 21 days; for up to 6 cycles) – In the Treatment Period, veliparib or placebo was given twice a day to patients for 7 days of each 3-week treatment cycle in combination with carboplatin/paclitaxel for up to 6 cycles of treatment. Carboplatin and paclitaxel were given to patients through injection into their veins.
- **Post-Treatment Period** – In the Post-Treatment Period, patients had visits with study doctors to check their overall health and monitor changes in their cancer.
- **Survival Follow-Up** – After a final visit (usually when the patient's cancer worsened), patients were called by study doctors for survival follow-up once every 2 months (to measure how long each patient lived).

4. What were the side effects?

Side effects are unwanted medical events that happen during a study. They may or may not be caused by the treatment in the study, and they may or may not be related to their disease.

A side effect is serious if it leads to death, is life-threatening, puts a patient in the hospital, keeps a patient in the hospital for a long time, or causes a disability that lasts a long time.

Related side effects are side effects that were considered by the study doctor to be at least possibly related to the study drug (veliparib or placebo). Remember, in a double-blinded study, neither the patients nor the study doctors knew who was given veliparib or placebo.

- About 32.0% of patients (155 patients) who received veliparib and 34.0% of patients (164 patients) who received placebo had serious side effects during the study.
- About 8.0% of patients (39 patients) who received veliparib and 8.1% of patients (39 patients) who received placebo had serious side effects considered related to study treatment.
- About 20.6% of patients (100 patients) stopped treatment with veliparib because of side effects during the study; 4.7% of patients (23 patients) stopped treatment with veliparib because of side effects considered related to study treatment.
- About 23.4% of patients (113 patients) stopped treatment with placebo because of side effects during the study; 6.0% of patients (29 patients) stopped treatment with placebo because of side effects considered related to study treatment.

During this study, 7.8% of patients (38 patients) who received veliparib died as a result of side effects; four of these side effects were considered to be possibly related to study treatment. Similarly, 9.1% of patients (44 patients) in the placebo group died during the study as a result of side effects; seven of these side effects were considered related to study treatment.

The table below shows information about the related serious side effects patients had during the study (in 4 or more patients), as well as related side effects patients had that led to the patient stopping the study treatment, and related side effects leading to death.

Overall Study		
	Placebo and chemotherapy (N=482 patients)	Veliparib and chemotherapy (N=485 patients)
Number of patients with related serious side effects	39 (8.1% of patients)	39 (8.0% of patients)
Related Serious Side Effects in 4 or More Patients		
• Anemia (low red blood cell count)	7 (1.5% of patients)	4 (0.8% of patients)
• Febrile neutropenia (fever with low neutrophil [a type of white blood cell] count)	11 (2.3% of patients)	10 (2.1% of patients)
• Nausea	4 (0.8% of patients)	0 (0.0% of patients)
• Pneumonia (lungs fill with fluid)	4 (0.8% of patients)	4 (0.8% of patients)
Number of patients who stopped taking study drug because of related side effects	29 (6.0% of patients)	23 (4.7% of patients)
Reasons for stopping (in at least 3 or more patients)	Asthenia (weakness), neutropenia (low white blood cell count), peripheral sensory neuropathy (nerve damage and pain), thrombocytopenia (low blood platelet count)	Asthenia
Number of related side effects leading to death	7 (1.5% of patients)	4 (0.8% of patients)
Related side effects	Cardiac arrest (heart stops), hemoptysis (coughing up blood), multiple organ dysfunction (more than two organ failures), pneumonia (lung infection), pulmonary hemorrhage (bleeding from the lung), respiratory tract infection (infection of the throat and airways to the lungs), and septic shock (an infection causing organ failure)	Blood creatinine increased (a waste product of muscles increases in the blood), cardiovascular insufficiency (heart failure), disease progression (cancer worsening), and sepsis (serious blood infection)

About 465 patients (95.9% of patients) who received veliparib and 462 patients (95.9% of patients) who received placebo had side effects during the study. The total number of patients that had side effects considered possibly related to veliparib was 216 patients (44.5% of patients) and to placebo was 219 patients (45.4% of patients).

The table below shows information about the common related side effects (in at least 10% or more patients) in this study. The most common related side effect was anemia (low red blood cell count).

Overall Study		
	Placebo and chemotherapy (N=482)	Veliparib and chemotherapy (N=485)
Number of patients with at least one related side effect	219 (45.4% of patients)	216 (44.5% of patients)
Anemia (low red blood cell count)	62 (12.9% of patients)	62 (12.8% of patients)
Neutropenia (low white blood cell count)	61 (12.7% of patients)	52 (10.7% of patients)
Nausea	57 (11.8% of patients)	48 (9.9% of patients)
Fatigue (tiredness)	61 (12.7% of patients)	54 (11.1% of patients)

About the same number of side effects were seen in both treatment groups.

5. What were the overall results of the study?

Current smokers did not show significant improvement in overall survival when they received veliparib compared to patients who received placebo (the main aim of the study). Overall survival in all of the patients, no matter their smoking status, was 1 month longer among patients who received veliparib compared to patients who received placebo. Overall side effects seen in treatment with veliparib taken in combination with carboplatin and paclitaxel were comparable to those seen in treatment with placebo in combination with carboplatin and paclitaxel. Side effects in this patient population were similar to side effects seen with the chemotherapy drugs used in other previous studies.

6. How has the study helped patients and researchers?

The results of this study found no significant benefit of treatment with veliparib in combination with carboplatin/paclitaxel compared to placebo in combination with carboplatin/paclitaxel. Researchers also learned that veliparib is well tolerated when added to treatment with chemotherapy. Findings from this study may be used in other studies to learn whether patients are helped by veliparib.

This summary only shows the results of this study, which may be different from the results of other studies. Patients should consult their physicians and/or study doctors with further questions about their individual care and should not make changes in their treatment based on the results of a single study.

7. Are there any plans for future studies?

There is a possibility for future studies that include veliparib. Studies of veliparib in other types of cancer are currently ongoing.

8. Who sponsored this study?

This study was sponsored by AbbVie. This summary was reviewed for readability by a patient advocacy group.

9. Where can I find out more information about this study?

Title of Study	Randomized, Double-Blind, Multicenter, Phase 3 Study Comparing Veliparib Plus Carboplatin and Paclitaxel Versus Placebo Plus Carboplatin and Paclitaxel in Previously Untreated Advanced or Metastatic Squamous Non-Small Cell Lung Cancer (NSCLC)
Protocol Number	M11-089
Clinicaltrials.gov	NCT02106546 https://clinicaltrials.gov/ct2/show/NCT02106546?term=M11-089&draw=2&rank=1
EudraCT	2013-005020-42 https://www.clinicaltrialsregister.eu/ctr-search/search?query=2013-005020-42
AbbVie.com	https://www.abbvie.com/our-science/clinical-trials/clinical-trials-data-and-information-sharing/results-summaries-for-study-participants.html
Publication Citation	Not available
Study Sponsor	AbbVie Inc. Phone: +1 800-633-9110 Email: abbvieclinicaltrials@abbvie.com

Thank You

AbbVie wants to thank all the participants for their time and effort that went into making this study possible.

Clinical study participants help advance science!

