

## A study of atezolizumab (immunotherapy) with chemotherapy compared with chemotherapy on its own in people with a type of lung cancer called ‘non-squamous non-small cell lung cancer’

See the end of the summary for the full title of the study.

### About this summary

This is a summary of the results of a clinical trial (called a ‘study’ in this document) – written for:

- Members of the public and
- People who took part in the study.

This summary is based on information known at the time of writing.

The study started in April 2015 and ended in July 2020. This summary includes the results that were analysed in March 2018 and was written after the study ended.

The results from this study may be different from other studies with the same medicine. One study can’t tell us everything about how safe a medicine is and how well it works. It takes lots of people in many studies to find out everything we need to know.

**This means that you should not make decisions based on this one summary – always speak to your doctor before making any decisions about your treatment.**

### Contents of the summary

1. General information about this study
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6. How has this study helped research?
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### Glossary

- NSCLC = non-small cell lung cancer

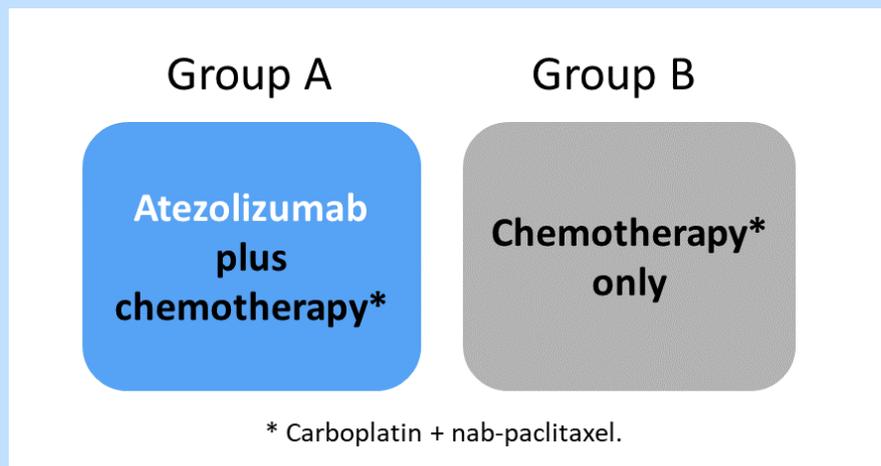
### Thank you to the people who took part in this study

The people who took part have helped researchers answer important questions about a type of lung cancer called ‘non-small cell lung cancer’ (NSCLC) and a new medicine being studied – ‘atezolizumab’ – taken together with chemotherapy.

## Key information about this study

### Why was this study done?

- This study was done to compare how 2 combinations of drugs worked in people with a type of NSCLC that's called 'non-squamous'. The drug combinations were:
  - The medicine being studied, called 'atezolizumab', taken together with existing chemotherapy called 'carboplatin + nab-paclitaxel'
  - Existing chemotherapy (carboplatin + nab-paclitaxel) on its own
- People were divided into 2 study groups as shown here, so the effects of the different combinations of medicines could be compared.



- This study included **723 people in 8 countries**. 705 of these people were given one of the treatments above.

### What were the results?

- The main findings were that:
  - For the people in **Group A**, their cancer did not get worse for about 7.0 months on average after starting the treatment, compared with about 5.5 months on average for people in **Group B**.
  - People in **Group A** lived for about 18.6 months on average from the start of the study, compared with about 13.9 months on average for people in **Group B**.

### How many people had serious side effects related to their treatment?

- **Group A**: 112 out of 473 people (24%) had serious side effects related to their treatment
- **Group B**: 30 out of 232 people (13%) had serious side effects related to their treatment
- These side effects are described in section 5.

## 1. General information about this study

### Why was this study done?

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People with the type of NSCLC called 'non-squamous' usually take medicine called chemotherapy that kills cancer cells or stops them from growing. 'Non-squamous' means that this type of NSCLC does not contain squamous cells. Squamous cells are a type of lung cell that is affected by cancer. Squamous cell cancers are usually found in the centre of the lung, but non-squamous cell cancers usually start around the edges of the lungs.

Chemotherapy that kills cancer cells using platinum is called 'platinum-based chemotherapy'. This type of treatment can use 2 different types of chemotherapy drugs taken together. However, chemotherapy may work for only a short time, and then the cancer gets worse again. Sometimes, chemotherapy may not work and the people with lung cancer may not live very long.

New medicines are needed to be able to treat the cancer – shrink the tumour –more effectively, and to help people to live longer. If the tumour shrinks, people may also be able to manage their cancer better. Immunotherapy is a new type of medicine that helps a person's own immune system attack cancer cells. **Immunotherapy may work better in some people than in others, or it may work for only a short time.** This may be because the cancer cells can hide from the immune system and/or learn to escape the immune system's attacks.

Some types of chemotherapy can 'wake up' the immune system so it is more likely to find cancer cells. Taking immunotherapy together with chemotherapy could help the immunotherapy to work better at attacking cancer cells.

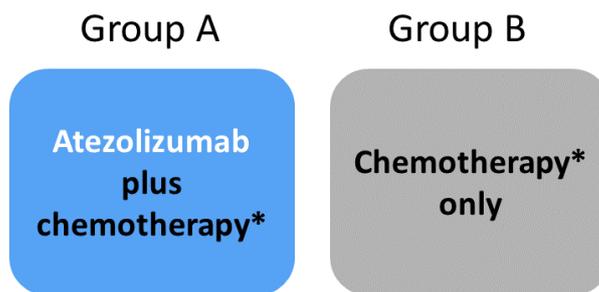
In this study, researchers wanted to see if taking an immunotherapy (atezolizumab) together with chemotherapy (carboplatin plus nab-paclitaxel) would help people with non-squamous NSCLC live longer. The researchers also wanted to see if this combination would stop the cancer from growing for longer than chemotherapy on its own. The people in this study did not take other medicine for advanced lung cancer before taking part in this study.

### What were the medicines being studied?

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This study looked at different combinations of a new medicine (immunotherapy) and existing chemotherapy medicines in 2 groups of people who had non-squamous NSCLC:

- **Group A: atezolizumab** (new medicine) plus **carboplatin + nab-paclitaxel** (existing chemotherapy)
- **Group B: carboplatin + nab-paclitaxel** (existing chemotherapy)



\* Carboplatin + nab-paclitaxel.

**Atezolizumab** is the medicine being studied here, in combination with chemotherapy.

- The body’s immune system fights diseases like cancer. However, cancer cells can block (stop) the immune system from attacking the cancer. Atezolizumab releases this blockage – meaning that the immune system is able to fight the cancer cells.
- When people take atezolizumab, their tumour (cancer) may get smaller.
- This medicine is a type of immunotherapy.

The existing **chemotherapy** medicines used in this study were:

- Carboplatin:
  - Carboplatin affects the genetic material in cells – the DNA. This stops cancer cells from dividing into new cells and kills them.
  - This medicine is a platinum chemotherapy drug.
- Nab-paclitaxel:
  - This medicine combines paclitaxel with a protein called albumin, which helps paclitaxel reach the tumour.
  - Nab-paclitaxel works by stopping cancer cells from dividing into new cells, so it blocks the growth of the tumour.

**After people stopped taking the study drugs, they were given ‘maintenance therapy’ – treatment to stop the cancer from coming back.**

### What did researchers want to find out?

- Researchers did this study to compare atezolizumab plus chemotherapy with chemotherapy on its own – to see how well atezolizumab plus chemotherapy worked (see section 4 “What were the results of the study?”).
  - People in **Group A** took atezolizumab with chemotherapy (carboplatin + nab-paclitaxel) to see whether this combination would work better than chemotherapy by itself (**Group B**) for people with non-squamous NSCLC.
- They also wanted to find out how safe the medicines were – by checking how many people had side effects in each treatment group and seeing how serious they were (see section 5 “What were the side effects?”).

**The main questions that researchers wanted to answer were:**

1. How much time was there between the start of treatment in **Group A** and **Group B** and the cancer getting worse?
2. How long did people in **Group A** and **Group B** live (during this study)?

## What kind of study was this?

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This was a **'Phase 3'** study. This means that before this study started, atezolizumab had been tested in a smaller number of people with non-squamous NSCLC. In this study, a larger number of people with this type of NSCLC took either atezolizumab combined with chemotherapy or chemotherapy on its own. Phase 3 studies are done in a large number of people to see if a drug works better than the standard existing treatment and is safe enough for it to be 'approved' by the health authorities as a treatment that can be prescribed by your doctor.

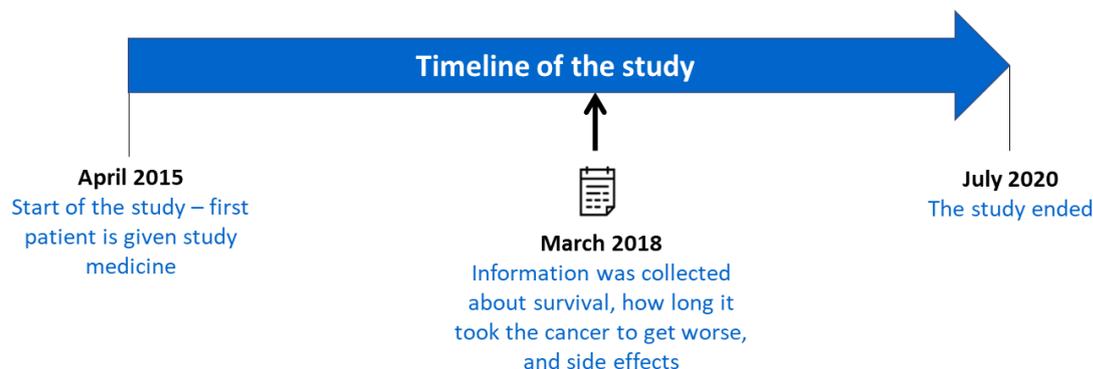
The study was **'randomised'**. This means that it was decided by chance which of the medicines people in the study would be given – like tossing a coin. Randomly choosing which medicine people take makes it more likely that the types of people in both groups will be a similar mix (for example, similar ages, similar races). Other than the different medicines being given in each group, all other care was the same.

This was an **'open label'** study. This means that both the people taking part in the study and the study doctors knew which of the study medicines people were taking.

## When and where did the study take place?

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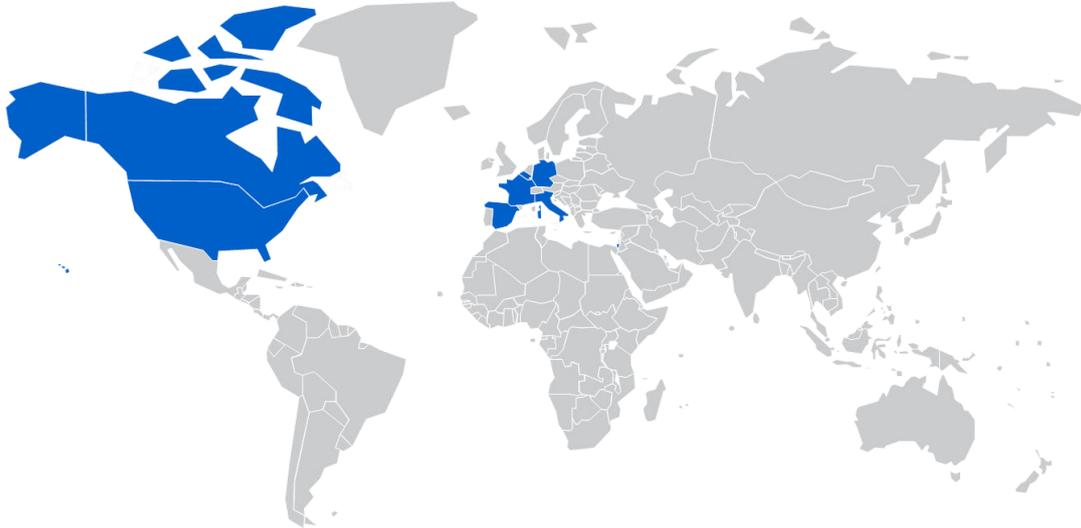
The study started in April 2015 and ended in July 2020. This summary was written after the study had ended.



The symbol on the timeline (📅) shows when the information shown in this summary was analysed (March 2018 – about 3 years after the study started).

The study took place at 131 hospitals and clinics in 8 countries – the United States, Canada, Belgium, France, Germany, Italy, Spain, and Israel.

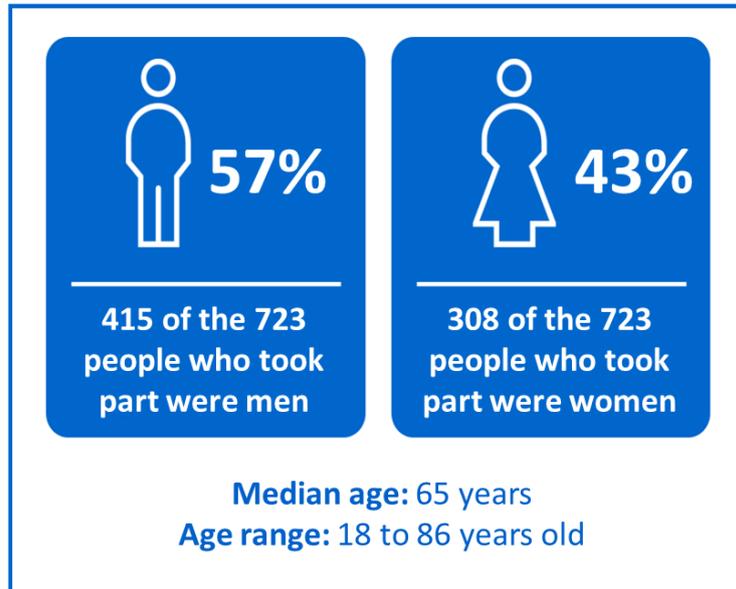
This map shows the countries where this study took place.



## 2. Who took part in this study?

In this study, 723 people with non-squamous NSCLC took part.

Here is more information about the people who took part in the study.



People could take part in the study if:

- They had advanced non-squamous NSCLC – called ‘advanced’ because the cancer had spread from where it started to nearby cells or to other parts of the body.
- They had not taken chemotherapy for advanced lung cancer before.
- They had allowed their doctor to take samples of their tumours.
- Their lung cancer either:
  - Did not have changes (mutations) in the genes called *EGFR* or *ALK*, or
  - Had mutations in *EGFR* or *ALK*, and any medicines they had taken to treat lung cancer with these mutations had not worked or caused so many side effects they had to stop taking the medicines.

People could not take part in the study if:

- They had cancer that had spread to the brain or spinal cord and had not been treated.
- They had an illness that causes their immune system to attack their own body (called an ‘autoimmune disease’).
- They had previously had other types of lung disease or lung infection.
- They had taken any medicines before that work like atezolizumab.

## 3. What happened during the study?

During the study, people were selected at random by a computer to get 1 of 2 treatments.

The treatment groups were:

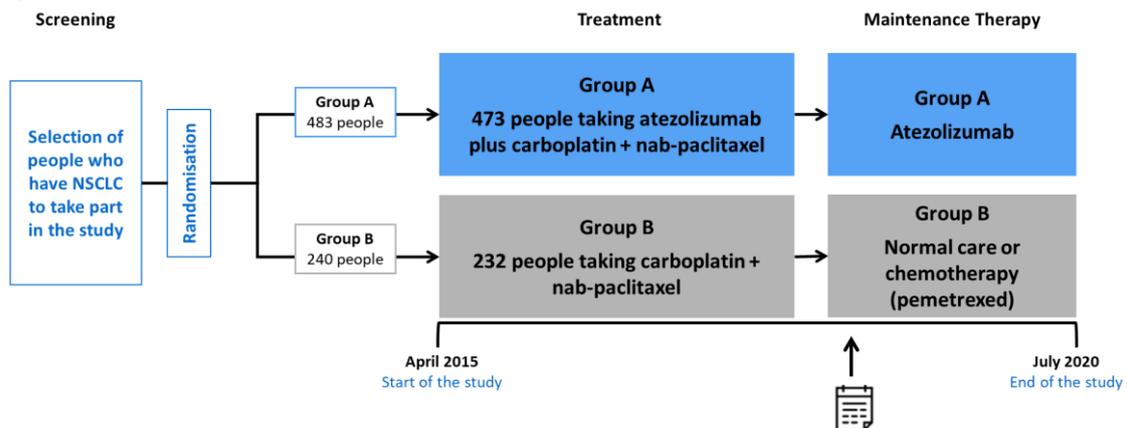
- **Group A:** atezolizumab (new medicine) plus carboplatin + nab-paclitaxel (existing chemotherapy)
- **Group B:** carboplatin + nab-paclitaxel (existing chemotherapy)

After people stopped receiving the study drugs, they were given ‘maintenance therapy’ – treatment to stop the cancer from coming back.

This table shows the number of people who took each study treatment, and how often the drugs were taken.

	Group A Atezolizumab plus carboplatin + nab- paclitaxel	Group B Carboplatin + nab- paclitaxel
Number of people in group (chosen by computer)	483	240
Number of people who took this medicine	473	232
Number of people who took this medicine and did not have changes (mutations) in the genes called <i>EGFR</i> or <i>ALK</i>	451	228
How the drugs were taken	Injected into a vein	Injected into a vein
When the drugs were taken in each 3-week treatment cycle	Atezolizumab: day 1 Carboplatin: day 1 Nab-paclitaxel: days 1, 8, 15	Carboplatin: day 1 Nab-paclitaxel: days 1, 8, 15
Maintenance therapy given after the main treatment was completed	Atezolizumab (injected into a vein)	Normal care or chemotherapy (pemetrexed)

This picture shows more information about what happened in the study – and what the next steps are.



The symbol on the timeline (📅) shows when the information shown in this summary was analysed (March 2018 – about 3 years after the study started).

- People in **Group A** were checked for about 18.5 months on average after starting the medicine, and people in **Group B** were checked for about 19.2 months on average.
- **When the study ended, the people who took part were asked to go back to their study centre for more visits to check their overall health.**

#### 4. What were the results of the study?

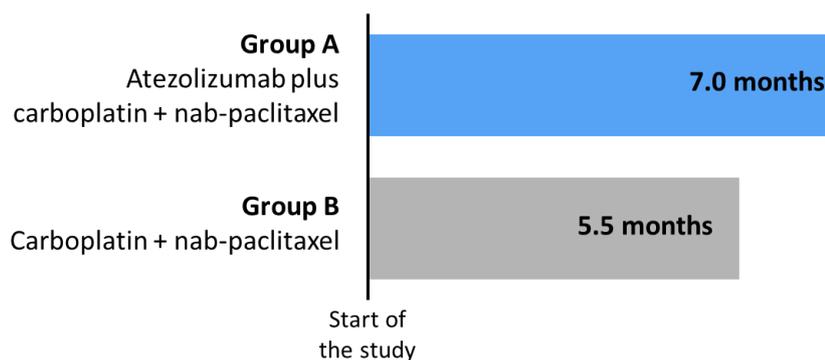
##### Question 1: How much time was there between the start of treatment and the cancer getting worse in **Group A** and **Group B**?

Researchers looked at how much time there was before the cancer became worse (in other words, spread to another part of the body, spread further, or grew larger as shown by their scans) in **Group A** and **Group B**. This information was collected from all the people in both groups from April 2015 until March 2018.

The results shown in this section are for the people who took the medicines and did not have any changes (mutations) in the genes called *EGFR* or *ALK*. Results were collected and analysed for 451 people in **Group A** and 228 people in **Group B**.

- In **Group A**, the cancer became worse after about 7.0 months, on average (in some people it took longer to become worse and in others it became worse sooner than 7.0 months).
- In **Group B**, the cancer became worse after about 5.5 months, on average (in some people it took longer to become worse and in others it became worse sooner than 5.5 months).

##### On average, how much time was there between the start of treatment and the cancer getting worse?



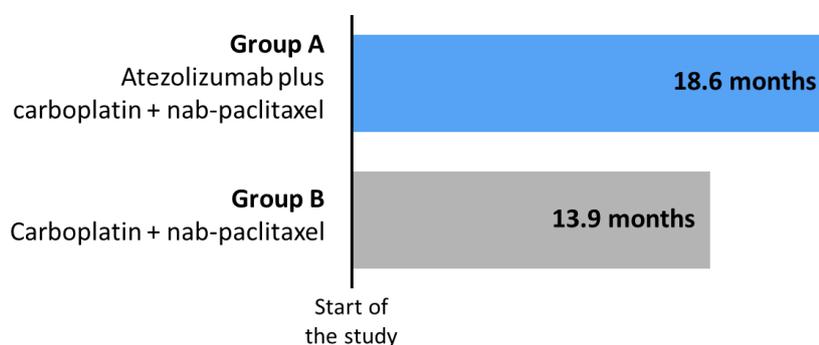
This information was collected from April 2015 until March 2018.

## Question 2: How long did people in **Group A** and **Group B** live (during the study)?

Researchers also looked at how long people lived on average during this study – this was compared between **Group A** and **Group B**. This information was collected from all the people in both groups from April 2015 until March 2018.

- People in **Group A** lived for about 18.6 months on average after starting the medicine.
- People in **Group B** lived for about 13.9 months on average after starting the medicine.
- These numbers for each treatment group are averages, which means that some people lived longer and some people died sooner.

On average, how long did people live in the study?



This information was collected from April 2015 until March 2018.

- In **Group A**, 226 out of 451 people (50%) died.
- In **Group B**, 131 out of 228 people (57%) died.

This section only shows the key results from this study. You can find information about all other results on the websites at the end of this summary (see section 8).

## 5. What were the side effects?

Side effects are medical problems (such as feeling dizzy) that may happen during the study.

- They are described in this summary because the study doctor believes the side effects were related to the treatments in the study.
- Not all of the people in this study had all of the side effects.
- Side effects may be mild to very serious.
- Side effects can be different from person to person.
- It is important to be aware that the side effects reported here are from this one study. Therefore, the side effects shown here may be different from those seen in other studies or those that appear on the medicine leaflets.
- Serious and common side effects are listed in the next sections.

The safety results shown in this section are for all the people who took the medicines during the study. Most people did not have any changes (mutations) in the genes called *EGFR* or *ALK*,

but some people were later found to have these mutations. Results were collected and analysed for 473 people in **Group A** and 232 people in **Group B**.

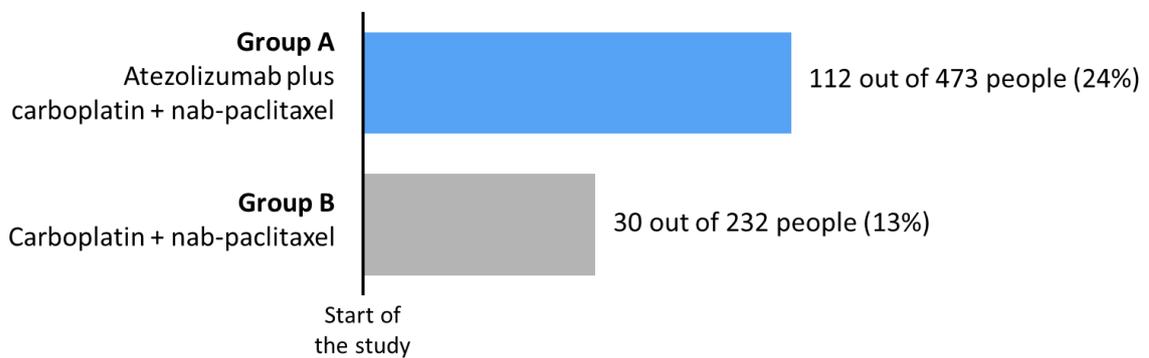
### Serious side effects

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A side effect is considered 'serious' if it is life-threatening, needs hospital care, or causes lasting problems.

During this study, approximately 20% of people had at least one serious side effect that was related to the medicine being taken. The number of people who had serious side effects in each group are shown in this picture.

#### How many people had at least one serious side effect?



This table shows the serious side effects that happened in more than 2% in each group (2 out of 100 people). Some people had more than one serious side effect.

<b>Serious side effects reported in this study</b>	<b>Group A</b> Atezolizumab plus carboplatin + nab-paclitaxel (473 people total)	<b>Group B</b> Carboplatin + nab-paclitaxel (232 people total)
Lung infection (pneumonia)	6% (28 out of 473)	6% (14 out of 232)
Lung infection (other)	3% (14 out of 473)	0.4% (1 out of 232)
Blood clot in the lung (pulmonary embolism)	3% (14 out of 473)	2% (5 out of 232)
Lung problems that make it hard to breathe	3% (12 out of 473)	1% (3 out of 232)
Shortness of breath	2% (11 out of 473)	Less than 1% (1 out of 232)
Lower-than-normal number of white blood cells	3% (14 out of 473)	Less than 1% (2 out of 232)
Lower-than-normal number of red blood cells	3% (12 out of 473)	3% (8 out of 232)
Fever and lower-than-normal number of white blood cells	2% (9 out of 473)	2% (5 out of 232)
Frequent, loose watery stools (diarrhoea)	3% (14 out of 473)	Less than 1% (2 out of 232)

Some people in the study died due to side effects that may have been related to one of the study medicines:

- 8 out of 473 people (2%) in **Group A** died.
- 1 out of 232 people (less than 1%) in **Group B** died.

During the study, some people decided to stop receiving their medicine because of side effects – this is shown in this picture.

#### How many people decided to stop taking their medicine because of side effects?



## Most common side effects

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The most common side effects related to the study medicines are shown in this table – these are the 10 most common side effects across all the treatment groups. Some people had more than one side effect.

<b>Most common side effects reported in this study</b>	<b>Group A</b> Atezolizumab plus carboplatin + nab-paclitaxel (473 people total)	<b>Group B</b> Carboplatin + nab-paclitaxel (232 people total)
Fewer-than-normal red blood cells	52% (248 out of 473)	47% (109 out of 232)
Fewer-than-normal white blood cells	46% (218 out of 473)	45% (104 out of 232)
Feeling sick (nausea)	44% (207 out of 473)	41% (96 out of 232)
Feeling tired	39% (185 out of 473)	39% (91 out of 232)
Frequent, loose watery stools (diarrhoea)	32% (150 out of 473)	24% (55 out of 232)
Hair loss (alopecia)	31% (145 out of 473)	26% (61 out of 232)
Low level of blood cell fragments that help blood to clot – called ‘platelets’	27% (127 out of 473)	25% (58 out of 232)
Not wanting to eat (less appetite)	23% (107 out of 473)	20% (46 out of 232)
Being sick (vomiting)	21% (99 out of 473)	14% (33 out of 232)
Constipation	15% (73 out of 473)	14% (33 out of 232)

## Other side effects

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You can find information about other side effects (not shown in the sections above) on the websites listed at the end of this summary – see section 8.

## 6. How has this study helped research?

The information presented here is from one study of 723 people with non-squamous NSCLC. These results helped researchers learn more about NSCLC and treatment with atezolizumab plus chemotherapy.

Overall, this study showed that for people who were given atezolizumab plus platinum-based chemotherapy, their cancer took longer to get worse and they lived slightly longer than people who were given the chemotherapy on its own. More people who were given atezolizumab plus chemotherapy had serious side effects than those who were given chemotherapy on its own. The people in this study did not have any new side effects that had not been seen before in people who took atezolizumab or chemotherapy in other studies.

## 7. Are there plans for other studies?

Other studies looking at the safety and effects of atezolizumab are happening. These studies are looking at the use of atezolizumab in different situations, for example:

- Together with other treatments
- Given before or after another treatment, to help that treatment work better
- Given to people as the first treatment for NSCLC that has spread to other parts of the body

## 8. Where can I find more information?

You can find more information about this study on the websites listed below:

- <https://clinicaltrials.gov/ct2/show/NCT02367781>
- <https://www.clinicaltrialsregister.eu/ctr-search/trial/2014-003206-32/results>
- <https://forpatients.roche.com/https://forpatients.roche.com/en/trials/cancer/lung-cancer/a-study-of-atezolizumab-in-combination-with-carboplatin-84489.html>

If you want to find out more about the results of this study, the full title of the paper we described here is: “Atezolizumab in combination with carboplatin plus nab-paclitaxel chemotherapy compared with chemotherapy alone as first-line treatment for metastatic non-squamous non-small-cell lung cancer (IMpower130): a multicentre, randomised, open-label, phase 3 trial”. The authors of the scientific paper are Howard West, Michael McCleod, Maen Hussein, Alessandro Morabito, Achim Rittmeyer, and others. The paper is published in *Lancet Oncology*, 2019, volume number 20, on pages 924-937.

## Who can I contact if I have questions about this study?

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If you have any more questions after reading this summary:

- Visit the ForPatients platform and fill out the contact form – <https://forpatients.roche.com/https://forpatients.roche.com/en/trials/cancer/lung-cancer/a-study-of-atezolizumab-in-combination-with-carboplatin-84489.html>
- Contact a representative at your local Roche office.

If you took part in this study and have any questions about the results:

- Speak with the study doctor or staff at the study hospital or clinic.

If you have questions about your own treatment:

- Speak to the doctor in charge of your treatment.

### **Who organised and paid for this study?**

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This study was organised and paid for by F. Hoffmann-La Roche Ltd who have their headquarters in Basel, Switzerland.

### **Full title of the study and other identifying information**

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The full title of this study is: “A Study of Atezolizumab in Combination With Carboplatin Plus (+) Nab-Paclitaxel Compared With Carboplatin + Nab-Paclitaxel in Participants With Stage IV Non-Squamous Non-Small Cell Lung Cancer (NSCLC) [IMpower130]”.

The study is known as ‘IMpower130’.

- The protocol number for this study is: GO29537.
- The ClinicalTrials.gov identifier for this study is: NCT02367781.
- The EudraCT number for this study is: 2014-003206-32.