Summary of Clinical Trial Results

A study to look at whether adding atezolizumab to chemotherapy works well in people with advanced breast cancer called 'triple-negative breast 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 it was written, following study completion.

The study started in August 2017 and ended in January 2023. This summary includes results that were collected and analysed in November 2019, September 2020 and January 2023. It was written after the study had ended and there were no remaining patients on the study.

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

- **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

Glossary

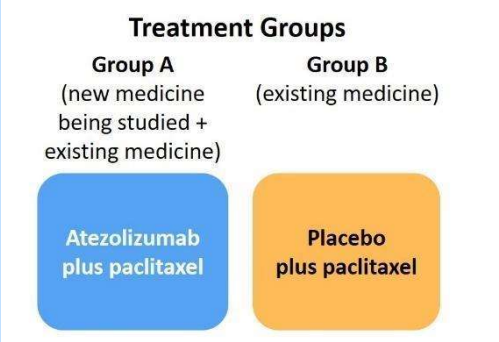
- **Triple-negative breast cancer (TNBC):** a kind of breast cancer that does not have any of the receptors that are commonly found in breast cancer: oestrogen, progesterone and human epidermal growth factor (HER2).
- **Immunotherapy (for cancer):** medicine used in cancer treatment to help the body's immune system attack tumours.
- **Programmed death-ligand 1 (PD-L1):** a protein that normally stops the immune system from attacking good cells. In cancer, tumour cells can use PD-L1 to hide from the immune system.

Thank you to the people who took part in this study

The people who took part have helped researchers to answer important questions about triple-negative breast cancer (TNBC) and the medicines studied – 'atezolizumab' combined with 'paclitaxel'.

Key information about this study

- This study was done to see whether atezolizumab combined with paclitaxel could lengthen the amount of time it took for people's cancer to get worse or help people live longer compared with placebo plus paclitaxel in people with locally advanced or metastatic TNBC.
- People were given an existing medicine (called 'paclitaxel') plus either the medicine being studied (called 'atezolizumab') or a placebo (no medicine). The study was 'randomised', which means it was decided by chance which treatment each person was given.



- This study included 651 people in 23 countries.
- The main findings were:
  - Adding atezolizumab to paclitaxel did not lengthen the amount of time it took for people's cancer to get worse compared with placebo plus paclitaxel. The differences between **Groups A** and **B** were not found to be meaningful differences and possibly due to chance alone.
    - For people in **Group A** whose tumours had cells with the protein called programmed death-ligand 1 (PD-L1), their cancer did not get worse until about 6.0 months from the start of the study, compared with about 5.7 months for those in **Group B**.
    - Overall, for people in **Group A**, their cancer did not get worse until about 5.7 months from the start of the study on average, compared with about 5.6 months for those in **Group B.**
  - People in **Group A** whose tumours had cells with the protein PD-L1 lived for 22.1 months on average; people in **Group B** whose tumours had cells with the protein PD-L1 lived for about 28.3 months on average. There was no evidence that being given atezolizumab shortened the amount of time that people lived. The differences between Groups A and B were not found to be real differences and might be caused by chance.
  - Overall, all people in **Group A** lived for 19.2 months on average, and people in **Group B** lived for 22.8 months on average. There was no evidence that being given atezolizumab shortened the amount of time that people lived. The differences between Groups A and B were not found to be meaningful differences and possibly due to chance alone.
  - People's quality of life at the start of treatment was maintained for a longer amount of time in **Group A** compared with **Group B**.

- The time to meaningful worsening of quality of life for people in **Group A** whose tumours had cells with the protein PD-L1 was about 17.2 months compared with about 12.0 months for those in **Group B**.
- The time to meaningful worsening of quality of life for all people in **Group A** was about 28.7 months, compared with about 17.4 months for those in **Group B**.

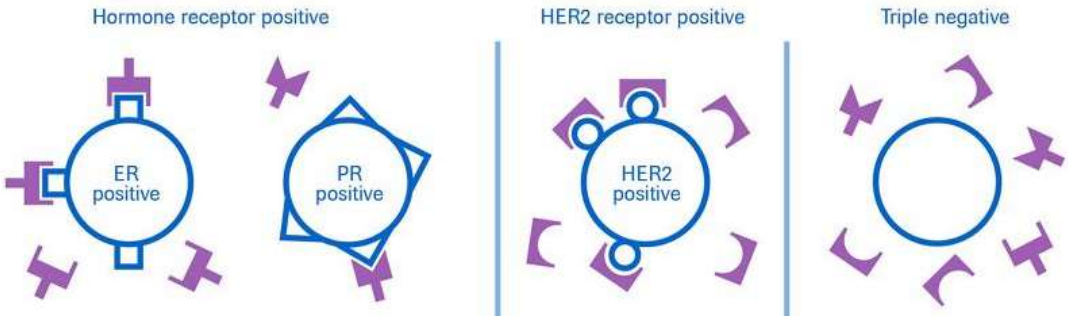
- About 26% of people (112 out of 432 people) in **Group A** had serious side effects, compared with about 18% of people (40 out of 217 people) in **Group B**.

1. General information about this study

Why was this study done?

TNBC is a type of breast cancer. There are different types of breast cancer, based on the presence or absence of receptors on the cells of the tumour. Knowing the characteristics of the cancer can help decide which treatments are likely to work. People who took part in this study had TNBC, which means their cancer cells do not have receptors for: 1) the hormone oestrogen, 2) the hormone progesterone or 3) the human epidermal growth factor receptor 2 (HER2) protein. Although therapies that target these receptors can be used to treat other types of breast cancer, these treatments do not work in people with TNBC. People with TNBC have a high unmet need; at the time this study was started, there were limited treatment options.

Types of breast cancer



ER = oestrogen receptor; HER2 = human epidermal growth factor receptor 2;
PR = progesterone receptor.

This study included people with TNBC that had spread from where it started to nearby tissue or lymph nodes (locally advanced cancer) and could not be removed by surgery. The study also included people with TNBC that had already spread to other parts of the body (metastatic TNBC). At the time the study started, chemotherapy was the main treatment option for this disease. The new cancer immunotherapy drug, atezolizumab, was studied in combination with paclitaxel (an existing, approved chemotherapy), as an alternative to paclitaxel alone, for people who have not received any other treatment for their metastatic TNBC.

This Phase 3 study looked at whether atezolizumab combined with paclitaxel could lengthen the amount of time before the cancer got worse or help people to live longer compared with placebo plus paclitaxel. The study also looked at how the medicines worked in people whose tumours had cells with the protein PD-L1, how the medicines affected people's quality of life,

and the safety (the side effects associated with a drug or treatment) of the two drugs when given together. The goal of the study was to see if atezolizumab should be offered with chemotherapy as treatment, instead of chemotherapy alone, for people who have not received any other treatment for their metastatic TNBC.

What were the medicines being studied?

A new combination of medicines was used in this study. Researchers compared atezolizumab plus paclitaxel (the new combination of medicines) to placebo plus paclitaxel to see what benefits or side effects are caused by the new medicine. Because of how the medicine works, atezolizumab is expected to work better on tumours with the PD-L1 protein. Based on earlier research and results from smaller clinical trials, researchers thought that this particular combination would work well in people with TNBC.

- **Group A: atezolizumab plus paclitaxel** (new combination of medicines)
- **Group B: placebo** (no medicine) **plus paclitaxel** (existing medicine)

One of the medicines in the new combination was called **'atezolizumab'**.

- You say this as 'a – teh – zo – liz – oo – mab'.
- This medicine is a type of medicine called 'immunotherapy'.
- The body's immune system fights diseases like cancer. However, cancer cells can block the immune system from attacking the cancer. One protein that can block the immune system is PD-L1. Atezolizumab releases this blockage – meaning that the immune system is able to fight the cancer cells.
- This may mean that when people are given atezolizumab, their tumour (cancer) may get smaller.

The other medicine in the new combination was called **'paclitaxel,'** which is an existing medicine given to people with TNBC. In addition to atezolizumab or placebo, all the people in this study were given paclitaxel.

- You say this as 'pak – li – tak – sel'.
- Paclitaxel works by stopping cancer cells from dividing into new cells, so it blocks the growth of the tumour.

Atezolizumab plus paclitaxel (the new combination of medicines) was compared with the combination of a **'placebo'** (no medicine) plus **paclitaxel** (the existing medicine).

- You say placebo as 'plah – see – bo'.
- The placebo looked the same as atezolizumab but did not contain any real medicine. This means it had no medicine-related effect on the body.

What did researchers want to find out?

- Researchers did this study to compare atezolizumab plus paclitaxel with placebo plus paclitaxel to see how well atezolizumab plus paclitaxel worked (see section 4 "What were the results of the study?").
- They also wanted to find out how safe the medicine was, by seeing how many people had side effects and how serious they were when taking each of the medicines during this study (see section 5 "What were the side effects?").

The main questions that researchers wanted to answer were:

1. Did giving the combination of atezolizumab plus paclitaxel to people whose tumours had cells with the protein PD-L1 lengthen the amount of time it took for their cancer to get worse compared with giving people placebo plus paclitaxel?
2. Did giving the combination of atezolizumab plus paclitaxel to people lengthen the amount of time it took for their cancer to get worse compared with giving people placebo plus paclitaxel?
3. Did giving the combination of atezolizumab plus paclitaxel to people whose tumours had cells with the protein PD-L1 help them live longer compared with giving people placebo plus paclitaxel?
4. Did giving people the combination of atezolizumab plus paclitaxel help them live longer compared with giving people placebo plus paclitaxel?
5. Did giving the combination of atezolizumab plus paclitaxel to people whose tumours had cells with the protein PD-L1 help to maintain their quality of life at the level it was at the start of treatment, compared with giving people placebo plus paclitaxel?
6. Did giving the combination of atezolizumab plus paclitaxel to people help to maintain their quality of life at the level it was at the start of treatment, compared with giving people placebo plus paclitaxel?

Other questions that researchers wanted to answer included:

7. How safe are these medicines? How many people had side effects when taking each of the medicines during this study?

What kind of study was this?

This study was a 'Phase 3' study. This means that the combination of atezolizumab plus paclitaxel had been tested in a smaller number of people with TNBC before this study. In this study, a larger number of people with locally advanced or metastatic TNBC were given either atezolizumab plus paclitaxel (the new treatment added to an existing treatment for TNBC) or a placebo plus paclitaxel. The study was done to find out if the new treatment worked to lengthen the amount of time it took for people's cancer to get worse and how long they lived. This study was also done to look at the side effects of atezolizumab plus paclitaxel, and the effect of the new treatment on people's quality of life. It can then be decided whether the treatment can be approved for doctors to prescribe.

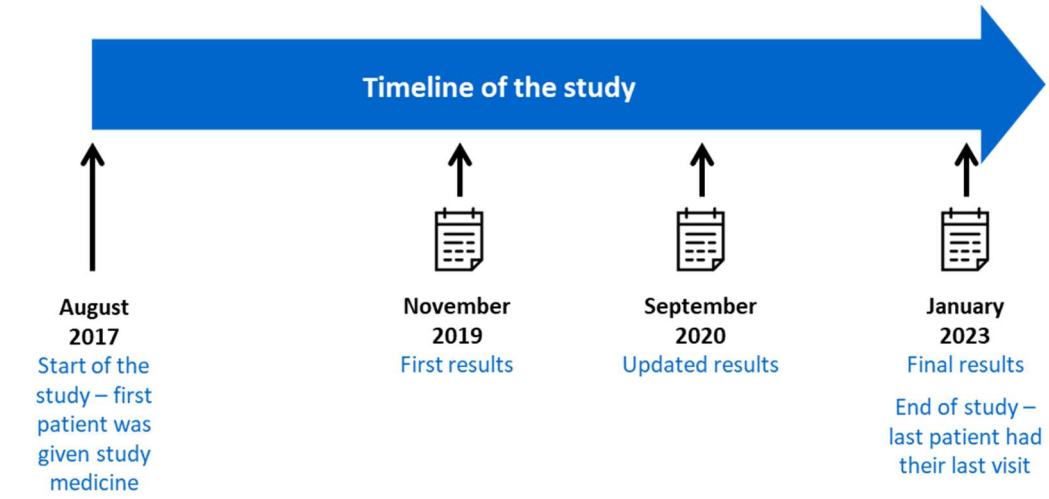
The study was 'randomised'. This means that it was decided by chance which of the medicines people in the study would have – like tossing a coin. Deciding by chance which medicine people take makes it more likely that the types of people in both groups (for example, age, race) will be a similar mix. Other than the medicines being tested in each group, all other aspects of care were the same between the groups.

This was a 'double-blind' study. This means that neither the people taking part in the study nor the study doctors knew which of the study medicines people were taking. 'Blinding' of a study is done so that any effect seen from the medicine is not due to something people would have expected to happen – if they had known which medicine they were taking.

When and where did the study take place?

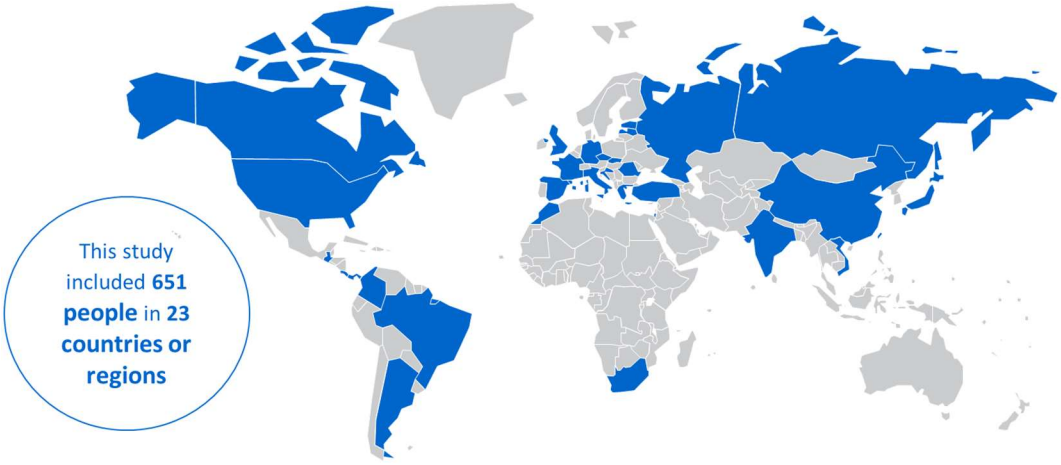
The study was started in August 2017 and ended in January 2023. This summary includes results that were collected and analysed in November 2019, September 2020 and

January 2023. It was written after the study had ended and there were no remaining patients on the study.



The symbols on the timeline (📋) show when the information in this summary was collected. The first results (collected in November 2019 – a little over 2 years after the study started) were used to look at how long it took for people's cancer to get worse. The updated results (collected in September 2020 – about 3 years after the study started) were used to look at how long people in the study lived. The final results (collected in January 2023 – a little under 5.5 years after the study started) were used to look at how the medicines affected people's quality of life.

The study took place at 150 study centres across 23 countries or regions. This map shows the countries where this study took place.

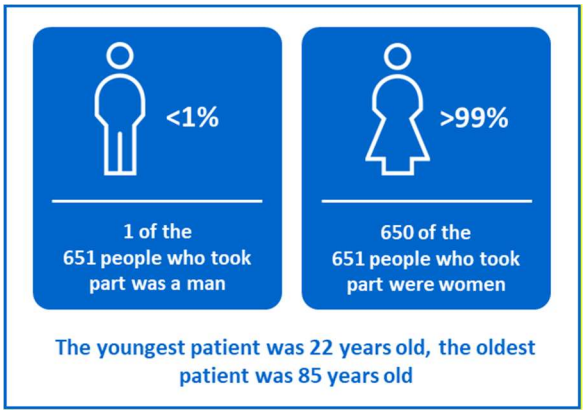


- Argentina
- Brazil
- Canada
- China
- Croatia
- Czech Republic
- France
- Germany
- Greece
- India
- Israel
- Italy
- Japan
- Morocco
- Romania
- Russia
- Slovakia
- South Africa
- Spain
- Turkey
- United Kingdom
- United States
- Vietnam

2. Who took part in this study?

In this study, 651 people with locally advanced or metastatic TNBC took part.

People who took part in the study were between 22 and 85 years of age. One of the 651 people (<1%) was a male, and 650 of the 651 people (>99%) were female. Here is more information about the people who took part in the study.



People could take part in the study if they:

- Were at least 18 years old.
- Had advanced TNBC in nearby cells that could not be removed completely through surgery, or TNBC that had spread to other parts of the body.
- Had a tumour that could be accurately measured in size.
- Had a tumour sample that could be tested for the protein PD-L1.
- Were able to perform activities as well or almost as well as they could before they had the illness.

People could not take part in the study if they:

- Had received any other treatment for advanced TNBC, or TNBC that had spread to other parts of the body.
- Had cancer that had spread to the brain, except for people who had been treated for cancer that had spread to the brain and did not have symptoms.
- Had an illness that affected the spinal cord.
- Were pregnant or were breastfeeding.

3. What happened during the study?

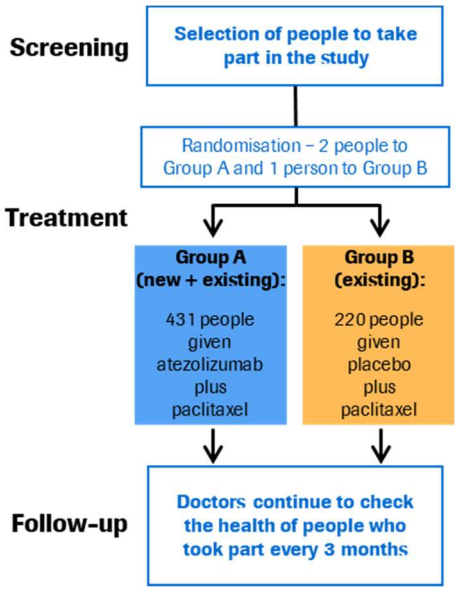
During the study, people were selected by chance to get one of two treatments; two people were selected for Group A for every one person selected for Group B. The treatments were selected at random – by a computer.

The treatment groups were:

- **Group A:** atezolizumab (the medicine being studied) plus paclitaxel (the existing medicine) – these people had atezolizumab injected into a vein once every 2 weeks. These people also had paclitaxel injected into a vein once a week for 3 out of every 4 weeks.

- **Group B:** placebo (no medicine) plus paclitaxel (the existing medicine) – these people were treated the same way as group A except, instead of atezolizumab, they were given a placebo (which looks the same as a medicine but does not contain any real medicine).

This picture shows what happened in the study.



This table shows the number of people enrolled into each arm of the study versus the actual number of patients who were given each study treatment. Sometimes people who enrol in a study do not end up taking part. For example, some people may decide not to be involved or may have other reasons for not taking part after enrolling. This occurred in two people (one from each group). In this study, two people in Group B also received treatment with atezolizumab by mistake.

	Group A Atezolizumab plus paclitaxel	Group B Placebo plus paclitaxel
Number of enrolled people randomly chosen to be included in each group	431	220
Number of people given at least one dose of medicine and observed for safety	432	217

4. What were the results of the study?

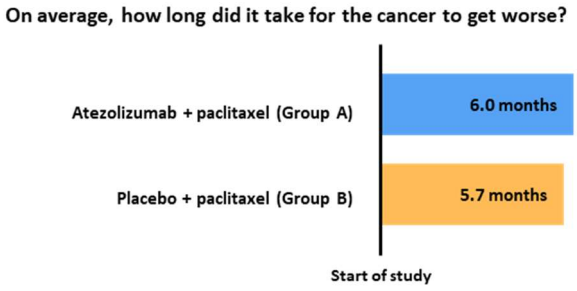
In this study, researchers looked at how long it took for people's cancer to get worse and how long people in the study lived.

The effects of the different treatments in Groups A and B were studied in all people enrolled in the study as a whole and in a smaller group of people whose tumours had cells with the protein PD-L1 (45% of all people in the study).

Question 1: Did giving the combination of atezolizumab plus paclitaxel to people whose tumours had cells with the protein PD-L1 lengthen the amount of time it took for their cancer to get worse compared with giving people placebo plus paclitaxel?

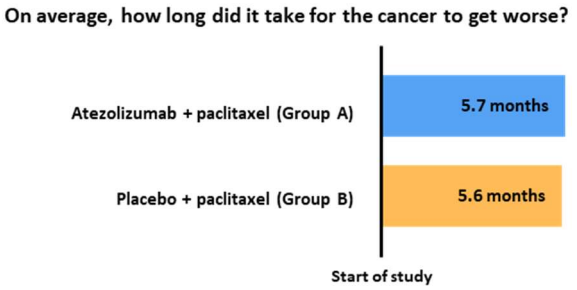
- When the first results were collected in November 2019, researchers found that adding atezolizumab to paclitaxel did not lengthen the amount of time people whose tumours had cells with the protein PD-L1 had before their cancer got worse compared with placebo plus paclitaxel. The differences between **Groups A** and **B** were not found to be real differences and might be caused by chance.

- In **Group A**, people's cancer got worse after 6.0 months on average. Some people's cancer got worse quicker than this, and some people's cancer took longer to get worse. In **Group B**, people's cancer got worse after an average of 5.7 months.



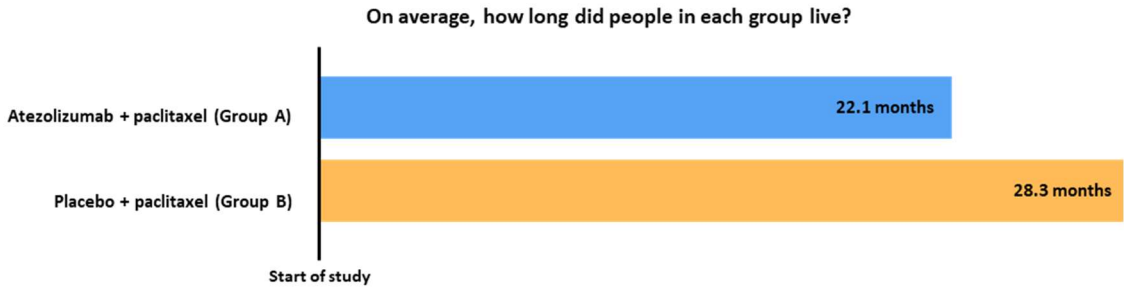
Question 2: Did giving people the combination of atezolizumab plus paclitaxel lengthen the amount of time it took for their cancer to get worse compared with giving people placebo plus paclitaxel?

- When the first results were collected in November 2019, researchers found that adding atezolizumab to paclitaxel did not lengthen the amount of time people had before their cancer got worse compared with placebo plus paclitaxel. The differences between **Groups A** and **B** were not found to be real differences and might be caused by chance.
- In **Group A**, people's cancer got worse after an average of 5.7 months. Some people's cancer got worse quicker than this, and some people's cancer took longer to get worse. In **Group B**, people's cancer got worse after an average of 5.6 months.



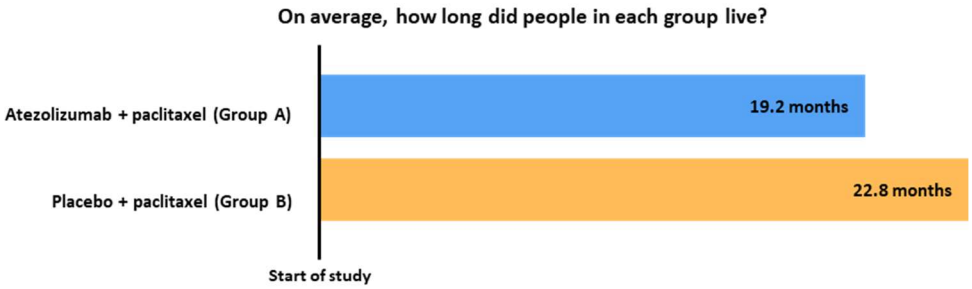
Question 3: Did giving the combination of atezolizumab and paclitaxel to people whose tumours had cells with the protein PD-L1 help them live longer compared with giving people placebo plus paclitaxel?

- The updated results collected in September 2020 told researchers how long people in the study lived for.
- People in **Group A** whose tumours had cells with the protein PD-L1 lived for about 22.1 months on average. People in **Group B** whose tumours had cells with the protein PD-L1 lived for about 28.3 months on average. Some people lived longer than this, and some did not live as long.
- There was no evidence that being given atezolizumab shortened the amount of time that people lived. The differences between **Groups A** and **B** were not found to be real differences and might be caused by chance.



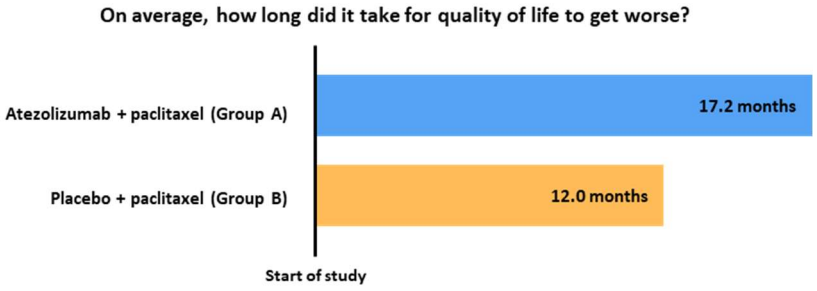
Question 4: Did giving people the combination of atezolizumab plus paclitaxel help them live longer compared with giving people placebo plus paclitaxel?

- The updated results collected in September 2020 told researchers how long people in the study lived.
- Overall, people in **Group A** lived for 19.2 months on average. Some people lived longer than this, and some did not live as long. People in **Group B** lived for 22.8 months on average.
- There was no evidence that being given atezolizumab shortened the amount of time that people lived. The differences between **Groups A** and **B** were not found to be real differences and might be caused by chance.



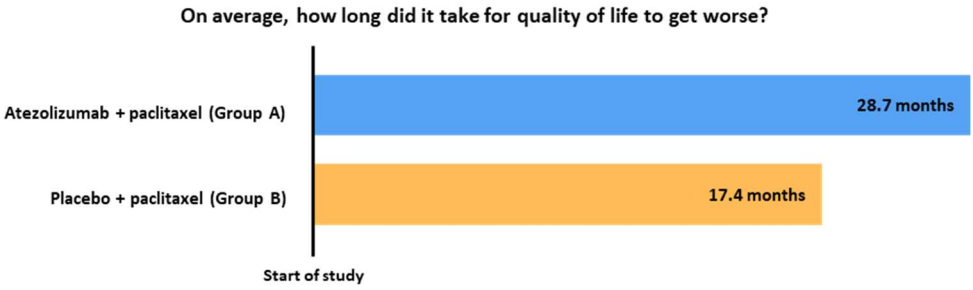
Question 5: Did giving the combination of atezolizumab plus paclitaxel to people whose tumour had cells with the protein PD-L1 help to maintain their quality of life at the level it was at the start of treatment, compared with giving people placebo plus paclitaxel?

- The final results collected in January 2023 told researchers how the medicines affected people's quality of life.
- Overall, people's quality of life at the start of treatment was maintained for a longer amount of time in **Group A** compared with **Group B**.
- The time to meaningful worsening of quality of life for people in **Group A** whose tumours had cells with the protein PD-L1 was 17.2 months on average. Some people's quality of life worsened slower than this, and some quicker. The time to meaningful worsening of quality of life for people in **Group B** whose tumours had cells with the protein PD-L1 was 12.0 months on average.



Question 6: Did giving the combination of atezolizumab plus paclitaxel to people help to maintain their quality of life at the level it was at the start of treatment compared with giving people placebo plus paclitaxel?

- The final results collected in January 2023 told researchers how the medicines affected people's quality of life.
- Overall, people's quality of life at the start of treatment was maintained for a longer amount of time in **Group A** compared with **Group B**.
- The time to meaningful worsening of quality of life for all people in **Group A** was 28.7 months on average. Some people's quality of life worsened slower than this, and some quicker. The time to meaningful worsening of quality of life for all people in **Group B** was 17.4 months on average.



This section only shows the key results from this study. You can learn 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 happen during the study.

- They are described in this summary because the study doctor believes the side effects could possibly be 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 and can be different from person to person.
- It is important to know 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 following sections.

Serious side effects

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

- During this study, about 1 in every 5 people (23%) had at least one serious side effect. About 26% of people taking atezolizumab plus paclitaxel had a serious side effect, compared with about 18% of people taking placebo plus paclitaxel. These serious side effects could have happened for reasons other than the treatments.

Some people in the study died because of side effects that may have been related to one of the study medicines. These were (*medical terms*):

- Ten out of 432 people (2%) in **Group A** (atezolizumab plus paclitaxel). One person each had a serious reaction to an infection called blood poisoning (*sepsis*), infection of the lungs (*pulmonary sepsis*), altered organ function (*multiple organ dysfunction syndrome*), heart failure (*cardiac failure*), inflamed and irritated muscles (*polymyositis*), and difficulty breathing (*respiratory distress*). Four people had unexplained deaths.
- Five out of 217 people (2%) in **Group B** (placebo plus paclitaxel). One person each had a serious reaction to an infection called blood poisoning (*sepsis*), heart failure (*cardiac failure*), and suicide. Two people had pneumonia.

During the study, some people decided to stop taking their medicine because of side effects:

- In **Group A** (atezolizumab plus paclitaxel), 96 out of 432 people (22%) stopped taking their medicine due to side effects.
- In **Group B** (placebo plus paclitaxel), 33 out of 217 people (15%) stopped taking their medicine due to side effects.

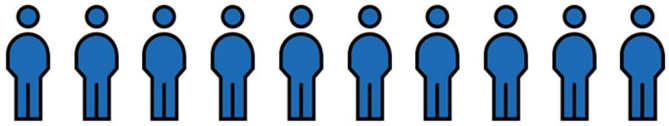
Most common side effects

During this study, almost ten out of every ten people (98%) had a side effect.

- About 99% of people in **Group A** (atezolizumab plus paclitaxel) had a side effect, and the majority of these (about 73%) were not considered serious.
- About 98% of people in **Group B** (placebo plus paclitaxel) had a side effect, and the majority of these (about 79%) were not considered serious.

These are all the side effects – including those that could have happened for reasons other than the treatments.

How many people overall (both groups A and B) had side effects?



Most people had at least one side effect

The most common side effects are shown in this table – these are the most common side effects in both treatment groups and could have happened for reasons other than the treatments. These side effects happened in at least ten out of 100 people (10%) in either treatment group. Some people had more than one side effect – this means that they are included in more than one row in the table.

Most common side effects reported in this study (*medical terms*)	**People taking atezolizumab plus paclitaxel** (432 people total)	**People taking placebo plus paclitaxel** (217 people total)
Hair loss (*alopecia*)	59% (253 out of 432)	54% (118 out of 217)
Low level of neutrophils (a type of blood cell; *neutropenia* and *neutrophil count decreased*)	39% (167 out of 432)	38% (83 out of 217)
Low level of red blood cells (*anaemia*)	30% (130 out of 432)	31% (68 out of 217)
Nerve damage in hands or feet (*neuropathy peripheral*)	29% (126 out of 432)	28% (60 out of 217)
Frequent, loose watery stools (*diarrhoea*)	31% (132 out of 432)	24% (51 out of 217)
Feeling tired (*fatigue*)	28% (119 out of 432)	26% (57 out of 217)
Feeling sick to stomach (*nausea*)	27% (118 out of 432)	25% (54 out of 217)
Low level of white blood cells (*white blood cell count decreased* and *leukopenia*)	28% (121 out of 432)	23% (50 out of 217)
Weakness or lack of energy (*asthenia*)	23% (101 out of 432)	22% (47 out of 217)
Liver, heart, or kidney damage – shown by higher levels of something called 'AST' in the blood (*AST increased*)	20% (87 out of 432)	18% (39 out of 217)
Liver damage – shown by higher levels of something called 'ALT' in the blood (*ALT increased*)	20% (86 out of 432)	18% (38 out of 217)
Cough	20% (86 out of 432)	17% (37 out of 217)
Constipation	19% (82 out of 432)	15% (33 out of 217)
Rash	18% (78 out of 432)	17% (36 out of 217)
Headache	14% (60 out of 432)	18% (38 out of 217)

Fever (*pyrexia*)	16% (70 out of 432)	12% (25 out of 217)
Vomiting	16% (71 out of 432)	10% (22 out of 217)
Joint pain (*arthralgia*)	16% (69 out of 432)	10% (21 out of 217)
Decreased appetite	15% (66 out of 432)	11% (23 out of 217)
Being short of breath (*dyspnoea*)	12% (50 out of 432)	11% (24 out of 217)
Swelling of the lower legs or hands (*oedema peripheral*)	12% (52 out of 432)	10% (22 out of 217)
Muscle pain (*myalgia*)	11% (48 out of 432)	12% (25 out of 217)
Pain in the hands or feet (*pain in extremity*)	11% (49 out of 432)	11% (23 out of 217
Weakness, numbness, and pain from nerve damage (usually in the hands and feet; *peripheral sensory neuropathy*)	10% (44 out of 432)	11% (23 out of 217)
Itching (*pruritus*)	11% (47 out of 432)	9% (19 out of 217
Tingling or pricking feeling (*paraesthesia*)	9% (40 out of 432)	10% (22 out of 217)
Low thyroid activity (*hypothyroidism*)	12% (50 out of 432)	3% (6 out of 217)
Problems falling and staying asleep (*insomnia*)	8% (33 out of 432)	10% (22 out of 217)

When only considering effects that the doctors said were related to the treatments, about 95% of people taking atezolizumab plus paclitaxel had side effects, compared with about 94% of people taking placebo plus paclitaxel.

Other side effects

You can learn 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 651 people with TNBC that has spread to other parts of the body. These results helped researchers learn more about this type of breast cancer and treatment with atezolizumab.

Overall, people who were given atezolizumab plus paclitaxel for TNBC that had spread to nearby cells or other parts of the body were just as likely to have their cancer get worse compared with people given placebo plus paclitaxel. People whose tumours had cells with the protein PD-L1 were not more likely to benefit from the combination of atezolizumab plus paclitaxel. There was no evidence that being given atezolizumab shortened the amount of time that people lived or maintained their quality of life at the level it was at the start of treatment.

No single study can tell us everything about the risks and benefits of a medicine. It takes lots of people in many studies to find out everything we need to know. The results from this study may be different from other studies with the same medicine.

- **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.**

7. Are there plans for other studies?

Studies with combinations of atezolizumab and other medicines in TNBC are still happening including IMpassion030 and IMpassion132. Information on these studies can be found at https://www.clinicaltrials.gov.

8. Where can I find more information?

You can learn more about this study on these websites:

- https://clinicaltrials.gov/ct2/show/NCT03125902
- https://www.clinicaltrialsregister.eu/ctr-search/search?query=2016-004024-29
- https://forpatients.roche.com/en/trials/cancer/bc/a-study-of-atezolizumab-and-paclitaxel-versus-placebo-and-paclit.html

If you would like to find out more about the results of this study, the full title of the relevant scientific paper is: "Primary results from IMpassion131, a double-blind, placebo-controlled, randomised phase III trial of first-line paclitaxel with or without atezolizumab for unresectable locally advanced/metastatic triple-negative breast cancer". The authors of the scientific paper are: D. Miles, J. Gligorov, F. André, D. Cameron, A. Schneeweiss, and others. The paper is published in the journal 'Annals of Oncology', volume number 32, on pages 994-1004.

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

If you have any further questions after reading this summary:

- Visit the ForPatients platform and fill out the contact form – https://forpatients.roche.com/en/trials/cancer/bc/a-study-of-atezolizumab-and-paclitaxel-versus-placebo-and-paclit.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?

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

The full title of this study is: “A Study of Atezolizumab and Paclitaxel Versus Placebo and Paclitaxel in Participants With Previously Untreated Locally Advanced or Metastatic Triple Negative Breast Cancer (TNBC) (IMpassion131)”

The study is known as ‘IMpassion131’.

- The protocol number for this study is: MO39196.
- The ClinicalTrials.gov identifier for this study is: NCT03125902.
- The EudraCT number for this study is: 2016-004024-29.