

Summary of Clinical Trial Results

A study of atezolizumab compared with placebo after surgery in people with kidney cancer with an increased risk of the cancer coming back

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 (September 2022).

The study started in January 2017 and is planned to end in December 2022. There are currently no people receiving study treatment. However, study doctors will still collect information until the study ends. This summary includes the results that were analysed up to May 2022.

The purpose of this study was to see if receiving atezolizumab after surgery helped to stop or delay kidney cancer from coming back. The results from this study may be different from other studies

with the same medicine. One study cannot 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 with your doctor before making any decisions about your treatment.**

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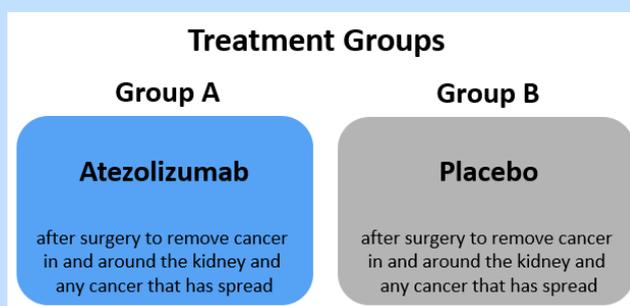
Thank you to the people who took part in this study

The people who took part have helped researchers answer important questions about kidney cancer and about treatment with a drug called 'atezolizumab', which was given in this study after the person had surgery to remove the cancer.

Key information about this study

Why was this study done?

- This study was done to compare the medicine being studied (called atezolizumab) with placebo (which looks the same as the study medicine but doesn't contain any real medicine and doesn't have any medicine-related effect on the body). Both were given after surgery in people with kidney cancer.
 - The purpose of this study was to see if atezolizumab given after surgery would help to stop or delay the kidney cancer from coming back.
 - It was decided by chance which treatment each person was given.



- This study included 778 people in 28 countries or regions (see map on page 5).

What were the results?

- The main findings were that:
 - In **Group A**, people's cancer did not come back for 57.2 months on average after starting the treatment, compared with 49.5 months on average for those in **Group B**.
 - However, the difference between **Group A** and **Group B** was not big enough to show researchers that giving atezolizumab helped to stop the cancer from coming back after surgery.

How many people had side effects?

- About 76% of people (296 out of 390 people) in **Group A** had side effects related to their treatment, compared with 53% of people (203 out of 383 people) in **Group B**.
- At the time of writing (September 2022), the study is still ongoing, and information about side effects is still being collected. However, no people are currently receiving study treatments. Since the study didn't determine that atezolizumab helped to keep people's cancer from coming back, no future checks will be done to see if atezolizumab helps people live longer. The study will be stopped in December 2022.

1. General information about this study

Why was this study done?

The standard treatment for people who have kidney cancer that hasn't spread far in the body is a type of surgery called 'nephrectomy' to remove the cancer from in and around the kidney. Sometimes the whole kidney may need to be removed. Additionally, some people may have cancer removed from other parts of their body, if the cancer has spread.

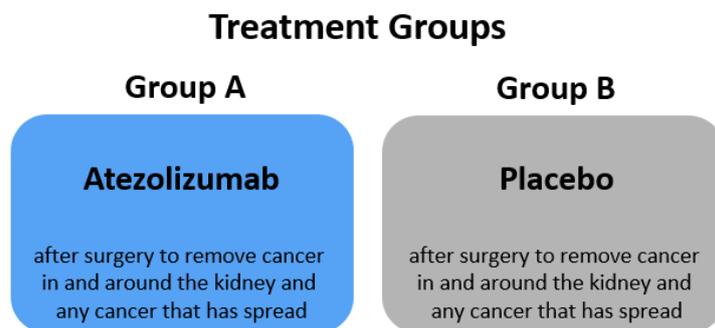
Although treatments are available, including surgery and medicines, there is currently no treatment that can cure all people with kidney cancer. Surgery does not work for all people – for some people, the cancer may come back, get worse, or spread to other areas of the body. New medicines are needed, in addition to surgery, to stop the cancer from coming back or getting worse – to help people live longer. Immunotherapy is a type of medicine that helps a person's own immune system attack cancer cells, and atezolizumab is an immunotherapy drug that is already used in other kinds of cancers.

In this study, researchers wanted to see if giving atezolizumab after surgery would help to stop the cancer from coming back. They compared people who were given the drug after surgery to people who were given a placebo instead. The people who took part in this study had already had surgery for their cancer before they were given this medicine.

What was the medicine being studied?

This study looked at a medicine called atezolizumab compared with placebo after surgery in two groups of people who had kidney cancer:

- **Group A: atezolizumab** (new medicine).
- **Group B: placebo**
 - These people were not given atezolizumab after surgery. Instead, they were given a placebo, which looks the same as the study medicine but doesn't contain any real medicine and doesn't have any medicine-related effect on the body.



The medicine being studied is '**atezolizumab**' (known by its brand name, Tecentriq®):

- You say this as 'a – teh – zo – liz – oo – mab'.
- The body's immune system fights diseases like cancer. However, cancer cells can block 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 are given atezolizumab, it may stop or delay their tumour (cancer) from coming back.

- This medicine is a type of medicine called ‘immunotherapy’.
- In this study, this medicine was given after people had surgery to remove the cancer to see if it would stop the cancer from coming back.

What did researchers want to find out?

- Researchers did this study to compare atezolizumab with placebo given after surgery – to see how well atezolizumab worked in people with kidney cancer (see section 4 “What were the results of the study?”).
 - People in **Group A** were given atezolizumab after surgery.
 - People in **Group B** were given placebo after surgery.
 - Researchers compared the two groups to see how well atezolizumab worked.
- Researchers also looked at how safe atezolizumab was – by seeing how many people in each treatment group had side effects and how serious these side effects were (see section 5 “What were the side effects?”).

The main questions that researchers wanted to answer were:

1. In **Group A** and **Group B**, how much time was there between the start of treatment and the cancer coming back?
2. How safe is atezolizumab? How many people in **Group A** and **Group B** had side effects, and how serious were they?

What kind of study was this?

This study was a ‘**Phase 3**’ study. This means that a large number of people with kidney cancer took either atezolizumab or placebo after surgery – this was to find out if atezolizumab helped to stop the people’s cancer from coming back. Phase 3 studies are done in a large number of people to see if a medicine works better than the usual treatment and is safe enough to be approved by the 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 two treatment groups people in the study would be in – like tossing a coin. Deciding by chance which group people will be in makes it more likely that the types of people in both groups will be similar (for example, in age and race). Other than the different study treatments given to people in each group (atezolizumab in **Group A** and placebo in **Group B**), all other care was the same.

This was a ‘**double-blind**’ study. This means that neither the people taking part in the study nor the study doctors or nurses 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 expected to happen – if they had known which medicine they were taking. Now that the study is ending, people in the study and their doctors have been told if they were in **Group A** or **Group B**.

When and where did the study take place?

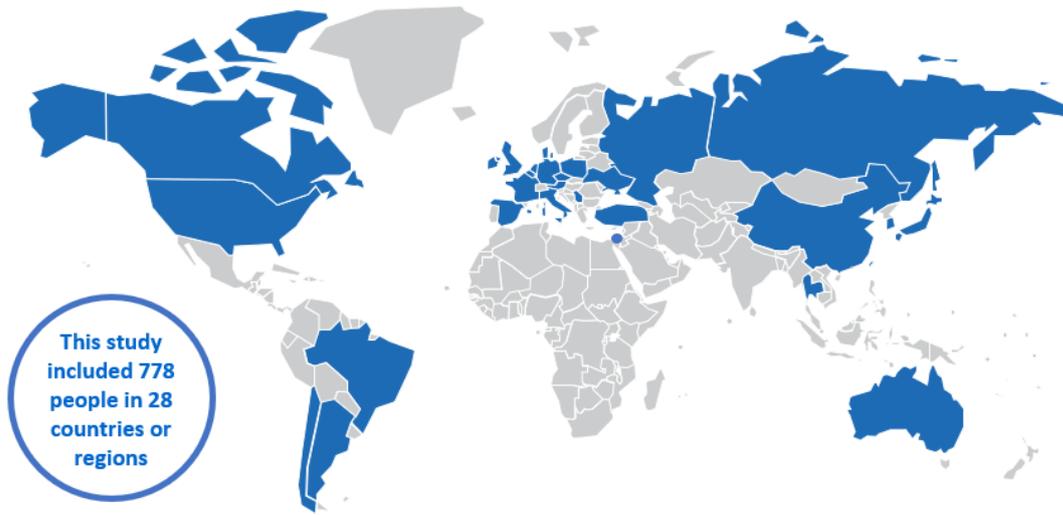
The study started in January 2017 and is planned to end in December 2022. Study doctors are still collecting information until the end of the study. However, people are no longer being enrolled.

At the time of writing this summary, the study is still happening. This summary only includes the results until May 2022.



The symbol on the timeline (📅) shows when the information shown in this summary was collected (May 2022 – about 5 years after the study started).

The study took place at 182 hospitals and clinics in 28 countries or regions. This map shows where this study took place.

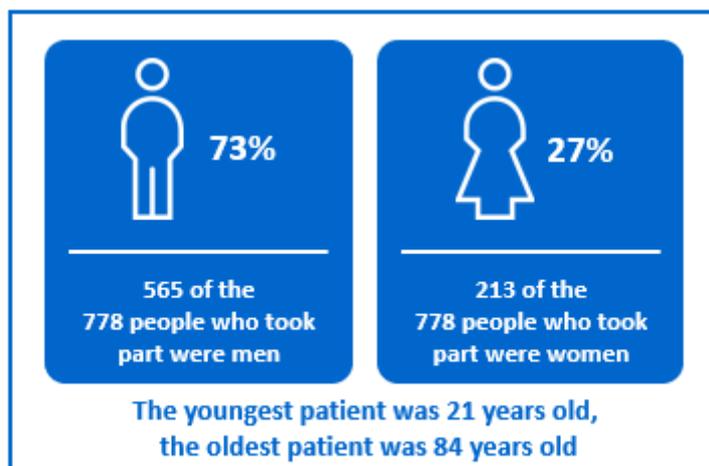


- Argentina
- Australia
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- Belgium
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- Canada
- Chile
- China
- Czech Republic
- Denmark
- France
- Germany
- Ireland
- Israel
- Italy
- Japan
- Republic of Korea
- Netherlands
- Poland
- Russian Federation
- Serbia
- Spain
- Taiwan
- Thailand
- Turkey
- Ukraine
- United Kingdom
- United States

2. Who took part in this study?

In this study, 778 people with kidney cancer 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 kidney cancer with increased risk of the cancer coming back after surgery (determined by the size of the tumour plus if and how much it had spread to other parts of the body).
- Had surgery to remove the kidney cancer. This includes removing cancer from the kidney and surrounding areas and any cancer that may have spread to other parts of the body.
- Had no cancer after surgery (determined in the study and confirmed by an outside doctor).

People could not take part in the study if they:

- Had received other anticancer treatment for their kidney cancer.

These are just some of the requirements that people needed to meet in order to be able to take part in this study. There were also other requirements that are not listed here.

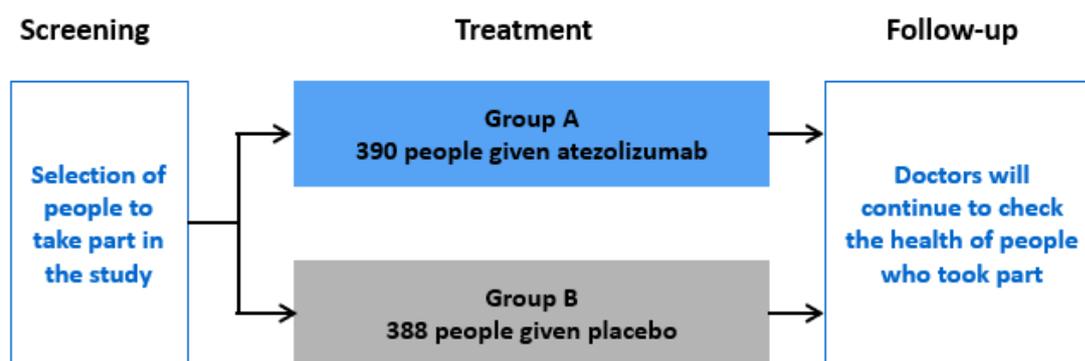
3. What happened during the study?

During the study, people were selected by chance to be in one of two treatment groups.

The treatment groups were:

- **Group A:** atezolizumab (new medicine).
- **Group B:** placebo (looks like new medicine but contains no active medicine).

This study is still happening. So, people are still going back to their study centre for visits – to check their overall health and collect information on side effects – until the study ends in December 2022. This picture shows more information about what has happened in the study so far – and what the next steps are.



This table shows the number of people who were given each study treatment, and how often the medicines were given. 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.

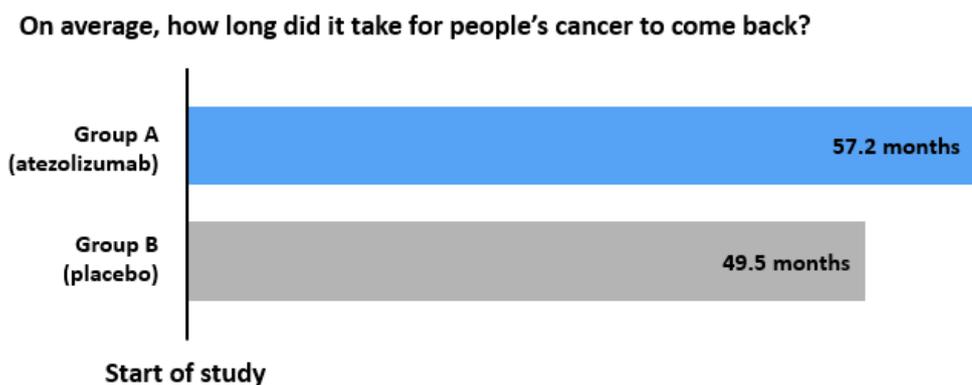
	Group A Atezolizumab	Group B Placebo
Number of enrolled people selected by chance to be included in each group	390	388
Number of people given medicine (atezolizumab or placebo)	390	383
How and when the medicine was given	Atezolizumab given by injection once every 21 days	Placebo given by injection once every 21 days

4. What were the results of the study?

How much time was there between the start of treatment and the cancer coming back in **Group A** and **Group B**?

Researchers looked at how much time there was before the cancer came back in **Group A** and **Group B**. This information was collected from all the people in both groups from January 2017 until May 2022.

- In **Group A**, the cancer came back after 57.2 months on average (in some people it took longer to come back, and in others it came back sooner).
- In **Group B**, the cancer came back after 49.5 months on average (in some people it took longer to come back, and in others it came back sooner).
- The difference between **Group A** and **Group B** was not big enough to show researchers that giving atezolizumab helped stop the cancer from coming back after surgery.
- This picture shows how long it took for the cancer to come back in each group.



This section only shows the key results from this study. You can find information about all other results on the websites listed 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.
- 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 in each 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 in the medicine leaflets.
- Common and serious side effects are listed in the following sections.

Most common side effects

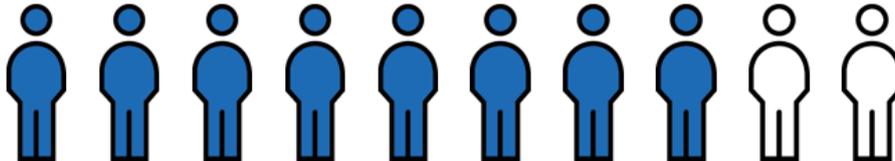
- In this study, 96% of people who received atezolizumab had a side effect of any kind, compared with 89% of people who received placebo.
- This table shows the most common side effects – these are the side effects that people in **Group A** had at least 5% more often than people in **Group B**. These side effects could have been serious (meaning an unwanted effect that is life-threatening, needs hospital care, or causes lasting problems) or not serious (meaning an unwanted effect, but one that was not life-threatening and did not require hospital care or have lasting effects). Some people had more than one side effect – this means that they are included in more than one row in the table.

Side effects reported in this study that were more common in people who received atezolizumab	Group A Atezolizumab (390 people total)	Group B Placebo (383 people total)
Joint pain	20% (78 out of 390)	15% (57 out of 383)
Itchy skin	19% (74 out of 390)	13% (48 out of 383)
Low thyroid activity	14% (56 out of 390)	3% (12 out of 383)
Rash	12% (46 out of 390)	5% (20 out of 383)
Fever	11% (43 out of 390)	4% (16 out of 383)
Dry mouth	7% (26 out of 390)	2% (6 out of 383)

Most common side effects related to atezolizumab

- The side effects shown in this section are thought to be caused by the treatment being studied – atezolizumab.
- During this study, 296 of the 390 people in **Group A** had at least one side effect that was related to atezolizumab.

How many people in Group A had at least one side effect related to atezolizumab?



Around **8 in every 10 people** had at least one side effect related to atezolizumab

This table shows the most common side effects related to atezolizumab – these are the side effects occurring in 20 or more people in the study. Some people have had more than one side effect.

Most common side effects related to atezolizumab reported in this study	Group A Atezolizumab (390 people total)	Group B Placebo (383 people total)
Feeling tired	20% (77 out of 390)	18% (69 out of 383)
Itchy skin	14% (56 out of 390)	10% (40 out of 383)
Low thyroid activity	13% (52 out of 390)	2% (8 out of 383)
Diarrhoea	12% (45 out of 390)	10% (39 out of 383)
Joint pain	9% (35 out of 390)	8% (30 out of 383)
Rash	7% (29 out of 390)	4% (14 out of 383)
Muscle aches	6% (25 out of 390)	3% (11 out of 383)
Low energy level	6% (24 out of 390)	3% (12 out of 383)
Feeling sick (nausea)	5% (21 out of 390)	7% (25 out of 383)
Dry mouth	5% (20 out of 390)	2% (6 out of 383)
Liver damage – shown by higher levels of something called ‘ALT’ in the blood	5% (20 out of 390)	2% (7 out of 383)

Serious side effects

- During this study, 34 of the 390 people (9%) in **Group A** had at least one serious side effect that was related to treatment with atezolizumab. A side effect is considered 'serious' if it is life-threatening, needs hospital care, or causes lasting problems.
- During the study, 45 of the 390 people (12%) in **Group A** had a side effect that made them decide to stop receiving atezolizumab.

Other side effects

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 in this summary is from one study of 778 people with kidney cancer. These results helped researchers learn more about this type of kidney cancer and treatment with atezolizumab after surgery.

Overall, the difference between **Group A** and **Group B** was not big enough to show researchers that giving atezolizumab helped to stop the cancer from coming back after surgery. Also, a new side effect suspected to be associated with atezolizumab was identified, which was dry mouth. All cases of dry mouth in the study were mild or moderate and did not affect the balance of risks and benefits of atezolizumab.

One study cannot 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. 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 with your doctor before making any decisions about your treatment.**

7. Are there plans for other studies?

There is another study looking at the safety and effects of atezolizumab in kidney cancer. However, in that study, atezolizumab is given together with another anti-cancer medicine.

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/NCT03024996>
- <https://www.clinicaltrialsregister.eu/ctr-search/search?query=2016-001881-27>
- <https://forpatients.roche.com/en/trials/cancer/rcc/a-study-of-atezolizumab-as-adjuvant-therapy-in-participants-with.html>

If you want to find out more about the results of this study, the full title of the relevant scientific paper is: “Adjuvant atezolizumab versus placebo for patients with renal cell carcinoma at increased risk of recurrence following resection (IMmotion010): a multicentre, randomised, double-blind, phase 3 trial”. The authors of the scientific paper are: Sumanta Kumar Pal, Robert Uzzo, Jose Antonio Karam, Viraj A. Master, Frede Donskov, Axel Bex, and others. The paper is published in the journal *The Lancet*, volume number 400, on pages 1103-1116.

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

If you have any more questions after reading this summary:

- Visit the ForPatients platform and fill out the contact form – <https://forpatients.roche.com/en/trials/cancer/rcc/a-study-of-atezolizumab-as-adjuvant-therapy-in-participants-with.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 as Adjuvant Therapy in Participants With Renal Cell Carcinoma (RCC) at High Risk of Developing Metastasis Following Nephrectomy (IMmotion010)”.

The study is known as ‘IMmotion010’.

- The protocol number for this study is: WO39210.
- The ClinicalTrials.gov identifier for this study is: NCT03024996.
- The EudraCT number for this study is: 2016-001881-27.