

Summary of Clinical Trial Results

A study to look at how well trastuzumab emtansine works in people with *HER2*-altered cancer (and not *HER2*-positive cancer) that has spread: part of the TAPISTRY study to understand how genetic testing can help doctors to decide which treatment is best for people living with solid tumours

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

About this summary

This is a summary of a part 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 February 2021. At the time of writing this summary, this study is still happening. This summary includes the complete results from one group of people (Group F) in the study, that were collected and analysed in September 2023.

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**

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Glossary

- HER2 = human epidermal growth factor receptor 2

Thank you to the people who took part in this study

The people who took part have helped researchers to answer important questions about *HER2*-altered solid tumours and the medicine studied – 'trastuzumab emtansine'.

Key information about this study

Why was the study done?

- This part of the TAPISTRY study was done to see how well a medicine that targets HER2 works against *HER2*-altered solid tumours that have spread

What was the treatment being studied and who was involved?

- In this study, people with *HER2*-altered solid tumours that had spread were given the medicine being studied (called 'trastuzumab emtansine')
- This study included 36 people in 11 countries. Of these, 35 people were given the study medicine

What were the results?

- The main finding was that 14% of people (5 out of 35 people) with *HER2*-altered cancer had a positive response to trastuzumab emtansine treatment. This means their cancer had shrunk
- Around 3% of people (1 out of 35 people) taking trastuzumab emtansine had serious unwanted effects that were considered related to treatment

1. General information about this study

Why was this study done?

Solid tumours are cancers that grow in organ systems throughout the body. These include cancers of the lung, breast, stomach and bladder.

Some solid tumours have biomarkers. Biomarkers are often used to help choose the best treatment for patients. These biomarkers can be proteins, hormones, genes, or gene alterations – 'mutations'. Gene mutations can help the cancer grow. A mutation is a change in a gene that can be sudden or passed on from parents so that the gene is different from what is found in healthy cells. A gene is a section of DNA that has instructions for making the body. Genes are passed on from parents to their children and contain all the information needed to make the body – from eye colour to blood type.

These mutations are usually not found on healthy cells. This means that mutations can act as targets for anticancer medicines to get rid of cancer cells while leaving healthy cells alone.

The TAPISTRY study looks at different targeted therapies in people with solid tumours. This large study involves people with different types of solid tumours who are put into groups that share the same biomarker. Each group is given an anticancer medicine that matches the target of their cancer.

This summary presents the results of one of these groups, Group F – people with '*HER2*-altered cancer'. These people had solid tumours with certain mutations in the *HER2* gene. *HER2* is also known as 'human epidermal growth factor receptor 2'. *HER2* is involved in normal cell growth.

What was the medicine being studied?

A medicine called ‘trastuzumab emtansine’ was the focus of this part of the study

- You say this as ‘tras – too – zoo – mab em-tan-seen’
- Trastuzumab emtansine is a medicine that ‘targets’ cancer cells by attacking HER2 proteins
- This means trastuzumab emtansine may stop *HER2*-altered cancer cells from growing
- Trastuzumab emtansine is approved in many countries for treating ‘*HER2*-positive’ breast cancers that have more copies of the *HER2* gene than usual. It is not approved for treating other types of *HER2*-positive cancer or *HER2*-altered cancers

What did researchers want to find out?

- Researchers did this study to see how well trastuzumab emtansine worked (see Section 4 “What were the results of the study?”)
- They also wanted to find out how safe the medicine was, by checking how many people had unwanted effects and seeing how serious they were (see Section 5 “What were the unwanted effects?”)

The main question that researchers wanted to answer was:

1. How many people had a positive response to the treatment?

What kind of study was this?

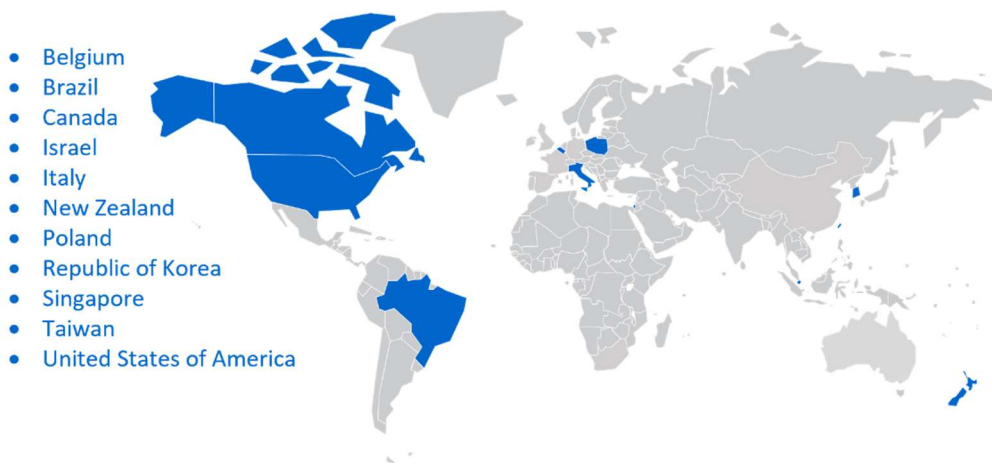
This study was a ‘Phase 2’ study. This means that trastuzumab emtansine had been tested in a number of people with *HER2*-altered solid tumours before this part of the TAPISTRY study. In this part of the study, only people with *HER2*-altered solid tumours took trastuzumab emtansine – this was to find out if it worked to shrink *HER2*-altered cancers.

This was an open-label study. This means everyone involved, including the participant and the study doctor, knew which study treatment the participant was given.

When and where did the study take place?

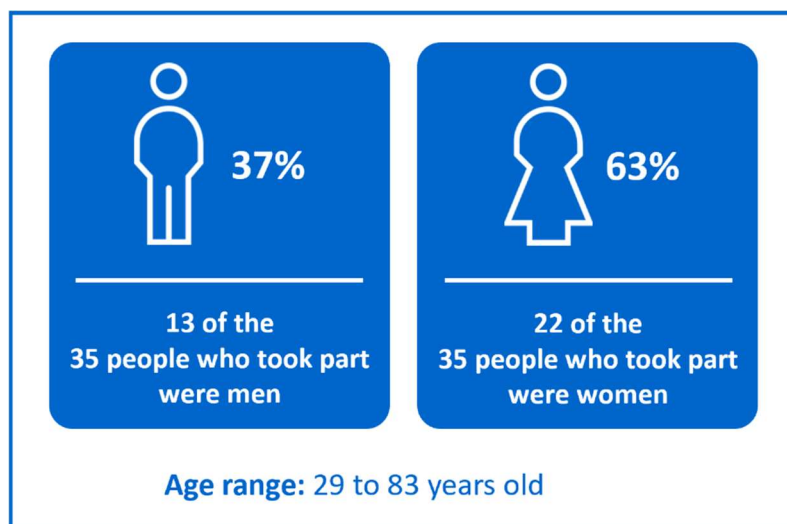
The study started in February 2021 and this group of people with *HER2*-altered cancers finished the study in September 2023. This summary was written after the study had ended for this group of people. Other groups of people (with cancer that has mutations other than *HER2*) are still taking part in the TAPISTRY study.

This part of the TAPISTRY study took place at 26 centres – across 11 countries in the Americas, Asia, Europe, and Oceania. The following map shows the countries where this study took place.



2. Who took part in this study?

- In this study, 36 people with *HER2*-altered cancer took part. Of these, 35 people were given the study medicine and are included in the results below.



People could take part in the study if:

- They were at least 12 years old
- Their solid tumour had certain mutations in the *HER2* gene (*HER2*-altered)

People could not take part in the study if:

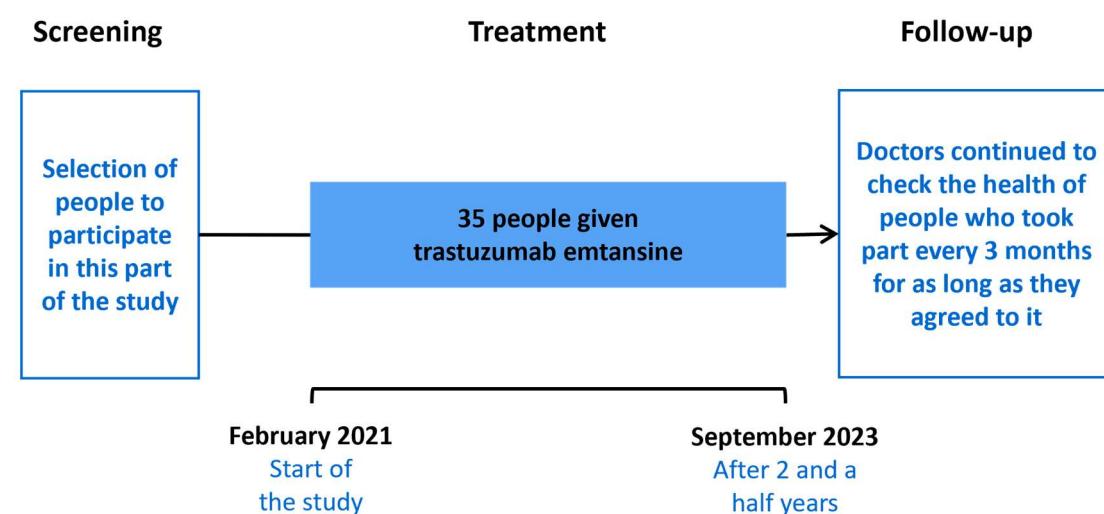
- Their cancer was *HER2*-positive – meaning that it has more copies of the *HER2* gene than usual
- They have certain medical conditions, including certain infections, heart or liver conditions, or they require oxygen to help them breathe
- Their cancer started in the brain or spinal cord, or has spread to the brain or spinal cord and causes symptoms
- They were pregnant or breastfeeding, or planning to become pregnant during or shortly after the study

3. What happened during the study?

People were given:

- **Trastuzumab emtansine** (the medicine being studied) – as a drip into the vein (infusion) every 3 weeks

People in the *HER2*-altered group of the study took the treatment for as long as it benefited them, or until their cancer got worse, they had unacceptable unwanted effects, or they decided to leave the study. When the study finished, the people who took part were asked to go back to their study centre for more visits – to check their overall health. Look below to see more information about what happened in the study.



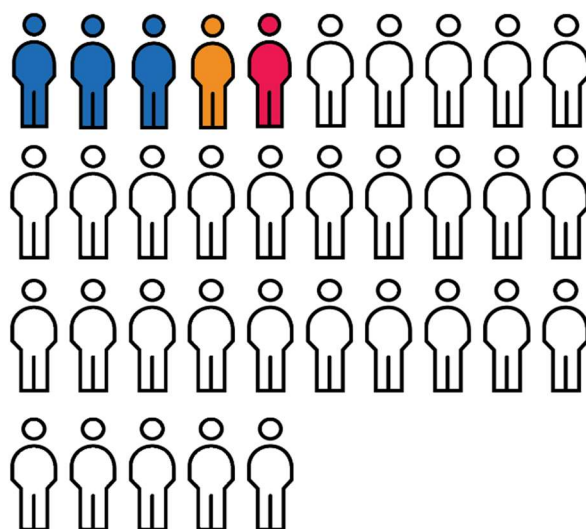
4. What were the results of the study?

Question 1: How many people had a positive response to the treatment?

Researchers looked at the number of people with cancer that shrunk or was not detectable on scans or tests after treatment.

- Out of 35 people who were given trastuzumab emtansine, 5 people (14%) had a positive response after an average of 7 months
 - All 5 people had cancer that shrunk but was still detectable on tests or scans

5 out of 35 people (14%) had a positive response to treatment



3 out of 5 people with breast cancer (60%) had a positive response to treatment



1 out of 11 people with non-small cell lung cancer (9%) had a positive response to treatment



1 person out of 1 with endometrial cancer (100%) had a positive response to treatment



The remaining 18 people did not respond to treatment

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 unwanted effects?

Unwanted 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 unwanted effects were related to the treatments in the study
- Not all of the people in this study had all of the unwanted effects
- Unwanted effects may be mild to very serious any can be different from person to person
- It is important to be aware that the unwanted effects reported here are from this single study. Therefore, the unwanted effects shown here may be different from those seen in other studies, or those that appear on the medicine leaflet
- Unwanted effects can vary from mild to very serious and may vary from person to person
- Serious and common unwanted effects are listed in the following sections

Serious unwanted effects

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

During this study, 1 person out of 35 (3%) had 4 serious unwanted effects that were considered related to the study medicine. These were:

- Bleeding and clotting disorder
- Liver damage
- Kidney damage
- Organ failure and low blood pressure due to an infection in the blood

One person in the study died due to unwanted effects (damage to the liver) that may have been related to the study medicine.

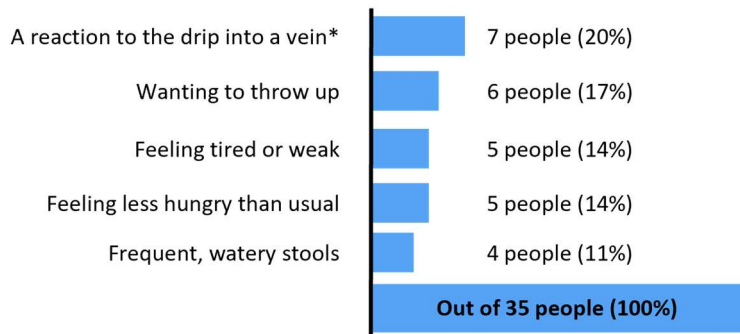
During the study, 4 people decided to stop taking their medicine because of unwanted effects.

Most common unwanted effects

During this study, around 7 out of every 10 people (25 out of 35 people) had an unwanted effect that was not considered serious.

The most common unwanted effects are shown in the following picture – these were reported in at least 1 in 10 people (10%). Some people had more than one unwanted effect – this means that they are included in more than one row in the picture.

How many people had each of these unwanted effects?



*Symptoms include throwing up, wanting to throw up, a feeling of coldness that makes the body shiver, low or high blood pressure, fever, pain or discomfort in the head, frequent watery stools, shortness of breath, and cough.

Other unwanted effects

You can find information about other unwanted 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 part of a single study of 35 people with *HER2*-altered solid tumours. These results helped researchers learn more about *HER2*-altered solid tumours and trastuzumab emtansine.

7. Are there plans for other studies?

Further studies with trastuzumab emtansine are planned.

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/results/NCT04589845>
- <https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-001847-16/results>
- <https://forpatients.roche.com/en/trials/cancer/solid-tumors/tumor-agnostic-precision-immuno-oncology-and-somatic-ta-50851.html>

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/solid-tumors/tumor-agnostic-precision-immuno-oncology-and-somatic-ta-50851.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: “Tumor-agnostic precision immuno-oncology and somatic targeting rational for you (TAPISTRY) phase II platform trial”.

The study is known as ‘TAPISTRY’.

- The protocol number for this study is: BO41932.
- The ClinicalTrials.gov identifier for this study is: NCT04589845.
- The EudraCT number for this study is: 2020-001847-16.