NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn about how well ^{68}Ga-FF58 can show certain types of solid tumors in PET scan images

Thank you!

Thank you to the participants who took part in the clinical trial for 4 types of **solid tumors**. Every participant helped the researchers learn more about the trial PET tracer **^{68}Ga-FF58**, also called [^{68}Ga]Ga-FF58.

Novartis sponsored this trial and believes it is important to share what was learned from the results of this trial with the participants and the public. We hope this helps the participants understand their important role in medical research.

Trial information

Trial number: CAAA504A12101

Novartis tracer studied: **^{68}Ga-FF58**, also called [^{68}Ga]Ga-FF58

Sponsor: Novartis

If you were a participant and have any questions about the results, please talk to the doctor or staff at the trial site.

This summary only shows the results of a single clinical trial. Other clinical trials may have different results.

What was the main purpose of this trial?

The purpose of this trial was to learn how well the trial tracer ^{68}Ga-FF58 can show tumors on **positron emission tomography (PET)** scan images in people with certain types of solid tumors. It also learned about the safety of ^{68}Ga-FF58. This trial was the first time that ^{68}Ga-FF58 was given to people.

One way to find tumors is to use an imaging test, such as PET with a radioactive tracer. However, current radioactive tracers may not correctly show all tumors in the body. It is important for doctors to find all tumors to decide on treatment options.

Solid tumors are cancers in organs and tissues, and not in body liquids such as blood. The 4 types of solid tumors in this trial were:

- **Glioblastoma multiforme (GBM)**, which is a fast-growing brain cancer
- **Breast cancer** that has spread to the brain
- **Pancreatic cancer**, which starts in the pancreas
- **Gastroesophageal (GE) cancer**, which starts in the stomach, esophagus (tube that connects the throat and stomach), or in the area where the stomach and esophagus meet

These types of tumors often have high levels of proteins on the surface of their cells called **integrins**.

A **radioactive tracer** is a substance with a small amount of radioactivity attached to it. Doctors use a radioactive tracer with imaging tests to look at cells and activity in the body. After the tracer is injected into the blood, it travels through the body and attaches to certain cells, such as tumor cells. The tracer gives off radioactive signals that the imaging test picks up to show these cells in scan images.

^{68}Ga-FF58 is a trial radioactive tracer that was developed to attach to the integrins on certain types of tumor cells.

PET (positron emission tomography) is an imaging test (scan) that can show cells in the body that the radioactive tracer attached to. This can help doctors find specific cells, like tumor cells.

The trial's purpose was to answer these main questions:

- How well did ^{68}Ga-FF58 show types of tumors on PET scan images?
- How long after participants received ^{68}Ga-FF58 did tumors show most clearly on PET scan images?
- How well did ^{68}Ga-FF58 show tumors compared to normal organs on PET scan images?
- What medical problems, also called adverse events, happened during this trial?

  ↳ An **adverse event** is any sign or symptom that participants have during a trial. Adverse events **may** or **may not** be caused by treatments in the trial.

How long was this trial?

The trial began in October 2021 and ended in July 2024. Each participant was in the trial for up to 6 weeks. The participants started the trial on different dates.

In June 2024, the sponsor ended this trial early due to business reasons. The decision was not due to safety concerns.

Who was in this trial?

14 participants with certain types of solid tumors received trial tracer in this trial – 6 men and 8 women. Participants' ages ranged from 27 to 67 years. Their average age was 54 years.

The number of participants by race is shown below.

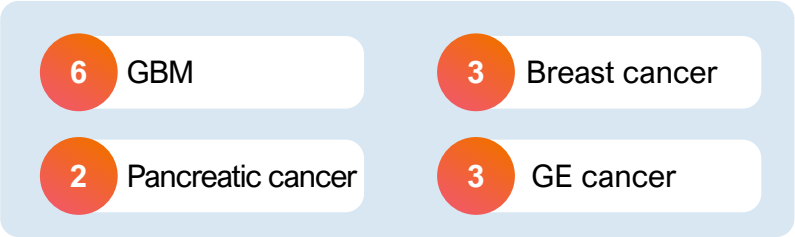
Race			
11	White	3	Not reported

The participants could take part in this trial if they:

- Had one of these types of solid tumors:
  - **GBM** that had come back or kept growing after treatment
  - **Breast cancer** that was metastatic and had spread to the brain
  - **Pancreatic cancer** that was **advanced or metastatic**
  - **GE cancer** that was advanced or metastatic
- Did not have a bleeding condition that made it hard to stop bleeding or needed treatment with blood thinners

Advanced or metastatic means the cancer came back or spread to other parts of the body

The number of participants with each type of cancer is shown below.



Trial participants were from 2 countries. The participants took part in:

- France | 3 participants
- Germany | 11 participants

What trial tracer did the participants receive?

The radioactive tracer was:

^{68}Ga-FF58, which was received as an injection in a vein.

The participants, researchers, and trial staff knew that all participants received ^{68}Ga-FF58.

What happened during this trial?

Before PET imaging Up to 4 weeks

The trial staff checked to make sure the participants could be in this trial.

During PET imaging 1 day

14 participants received 1 injection of ^{68}Ga-FF58 into a vein in the arm.

Participants had PET scans at 30 minutes, 1 hour, and 2 hours after receiving the trial tracer. They also had Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) scans. CT and MRI scans show detailed images of the inside of the body. The CT and MRI scans helped researchers better understand the PET scan results.

After PET imaging 2 weeks

Trial staff checked participants for any medical problems for up to 2 weeks after the injection of ^{68}Ga-FF58.

Trial staff checked the participants' general health throughout the trial.

What were the main results of this trial?

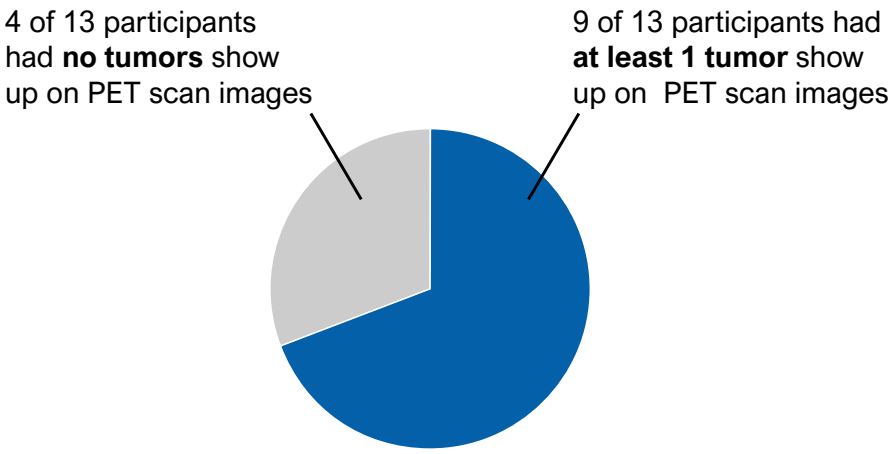
How well did ^{68}Ga-FF58 show types of tumors on PET scan images?

Of 13 participants with available scan images, 9 had at least 1 tumor show up on PET scan images using **^{68}Ga-FF58**. 4 participants had no tumors show up.

To learn this, the researchers looked at the PET scan images using **^{68}Ga-FF58** for each participant. They recorded if they saw tumors or not.

Number of participants who had at least 1 tumor show up on PET scan images using ^{68}Ga-FF58

This chart includes 13 participants with certain types of solid tumors who had results available.



The PET scan images showed a total of 14 tumors in the 9 participants. However, the participants may have had more tumors that the PET scan images did not show.

How long after participants received ^{68}Ga-FF58 did tumors show most clearly on PET scan images?

^{68}Ga-FF58 showed tumors most clearly on PET scan images 1 hour after it was given.

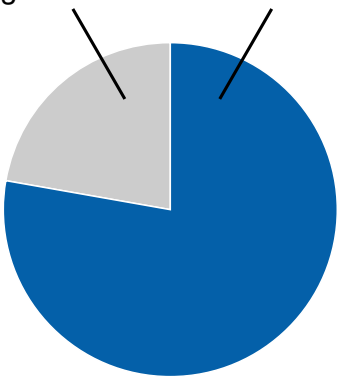
To learn this, the researchers looked at how much **^{68}Ga-FF58** attached to tumors at 30 minutes, 1 hour, and 2 hours after it was given.

Number of participants whose tumours showed most clearly on PET scan images 1 hour after ^{68}Ga-FF58 was given

This chart includes 9 participants who had tumors show up on PET scan images. 4 participants had no tumors show up on PET scan images.

2 of 9 participants **did not have** tumors show most clearly on PET scan images **1 hour** after **^{68}Ga-FF58** was given

7 of 9 participants **had** tumors show most clearly on PET scan images **1 hour** after **^{68}Ga-FF58** was given



How well did ^{68}Ga-FF58 show tumors compared to normal organs on PET scan images?

^{68}Ga-FF58 attached to normal organs and tumors based on PET scan images. More **^{68}Ga-FF58** attached to normal organs than to tumors, except in the brain.

To learn this, the researchers looked at how much **^{68}Ga-FF58** attached to tumors compared to normal organs.

What medical problems, also called adverse events, happened during this trial?

Trial doctors keep track of all medical problems, also called **adverse events**, that happen in trials. They track adverse events even if they think the adverse events are not related to the trial tracer.

Many trials are needed to know if a trial tracer causes an adverse event.

This section is a summary of the adverse events that happened until 2 weeks after the injection of the trial tracer.

An **adverse event** is:

- Any **sign or symptom** that the participants have during a trial
- Considered **serious** when it is life-threatening, causes lasting problems, the participant needs hospital care, or results in death

Adverse events **may** or **may not** be caused by the tracer in this trial.

No participants had adverse events that were considered serious. 2 out of 14 participants had other (not including serious) adverse events. No participants died during this trial. No participants left the trial due to an adverse event. The researchers concluded there were no new safety concerns for ^{68}Ga-FF58 in this trial.

What serious adverse events did the participants have?

No participants had serious adverse events, and none died.

What other (not including serious) adverse events did the participants have?

2 participants had other adverse events. Each adverse event was reported by 1 of the 2 participants:

- **Feeling tired and falling asleep during the day** (hypersomnia)
- **Feeling weak and tired** (fatigue)
- **Leaking urine or peeing by accident** (urinary incontinence)
- **Memory loss** (amnesia)
- **Confusion as to time, place, or identity** (disorientation)
- **Indigestion** (dyspepsia)
- **Belly discomfort or pain** (abdominal discomfort)

What was learned from this trial?

Researchers learned about how well ^{68}Ga-FF58 can show tumors on PET scan images in people with certain types of solid tumors. It also learned about the safety of ^{68}Ga-FF58. The sponsor ended this trial early due to business reasons.

The researchers concluded that:

- Of the 13 participants with available scan images, 9 had at least 1 tumor show up on PET scan images using ^{68}Ga-FF58
- ^{68}Ga-FF58 showed tumors most clearly on PET scan images 1 hour after it was given
- Overall, more ^{68}Ga-FF58 attached to normal organs than to tumors, except in the brain
- There were no new safety concerns for ^{68}Ga-FF58 in this trial

When this summary was written, the sponsor was not considering future trials of ^{68}Ga-FF58 in people with certain advanced solid tumors.

Where can I learn more about this trial?

More information about the results and adverse events in this trial can be found in the scientific summary of the results available on the Novartis Clinical Trial Results website **www.novctrd.com**

Follow these steps to find the scientific summary:

Go to **www.novctrd.com** → Click **Clinical Trial Results** → Accept the terms **I accept** → Search by study number **CAAA504A12101**

For more information about this trial, go to this website:

- **clinicaltrials.gov** – search using the number **NCT04712721**

Other trials of ^{68}Ga-FF58 may appear on the public website above. When there, search for ^{68}Ga-FF58 or [^{68}Ga]Ga-FF58.

Full clinical trial title: Phase I, open-label, multicenter study to evaluate the imaging performance, safety, biodistribution and dosimetry of [^{68}Ga]Ga-FF58 in adult patients with selected solid tumors expected to overexpress αvβ3 and αvβ5 integrins.

Novartis is a global healthcare company based in Switzerland that provides solutions to address the evolving needs of patients worldwide.

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