

Clinical trial results summary

A clinical trial to learn about the safety and effects of PDR001 with other cancer treatments in people with metastatic colorectal cancer

Protocol number: CPDR001I2101

Our thanks to the participant!



Novartis, the sponsor of this clinical trial, would like to thank the participant who took part in this trial for the drug PDR001, also known as spartalizumab. They helped researchers learn more about how PDR001 works in people with metastatic colorectal cancer.

Clinical trial participants belong to a large community of people around the world. Their invaluable contribution to medicine and healthcare is greatly appreciated.

This summary only shows the results of one clinical trial. Other clinical trials may have different findings. Researchers and health authorities look at the results of many clinical trials to understand which drugs work and if they are safe. It takes many people in multiple clinical trials around the world to advance medical science and healthcare.

Why was this research needed?

Researchers are looking for a better way to treat **metastatic colorectal cancer**, which is cancer that started in the colon or rectum and spread to other parts of the body. This trial looked at a specific type of metastatic colorectal cancer called **MicroSatellite Stable (MSS) colorectal cancer**. MSS is the most common type of colorectal cancer and is harder to treat than other types. The usual treatment for metastatic colorectal cancer involves a combination of surgery, chemotherapy, and radiation therapy.

Immunotherapy is a newer kind of cancer treatment that uses the body's own immune system to help detect and fight cancer. Immunotherapy often has fewer side effects than other cancer treatments and can prevent cancers from coming back. Research has found it only works for certain types of colorectal cancers, and often doesn't work for MSS colorectal cancer.

PDR001 is an immunotherapy that has been tested in other types of cancer. Researchers want to learn more about PDR001 and if it could help people with metastatic MSS colorectal cancer. To do this, they designed this clinical trial to learn about the safety of PDR001 when given together with other commonly prescribed treatments for MSS colorectal cancer.

Trial treatments

The drugs given in this trial were:



PDR001, also known as spartalizumab (pronounced spar-ta-LIZ-uh-mab): A trial drug that has been tested in certain types of cancer



mFOLFOX6, also called modified FOLFOX-6: A commonly prescribed chemotherapy treatment for colorectal cancer



bevacizumab (pronounced bev-a-ciz-u-mab): A commonly prescribed drug that is sometimes used with mFOLFOX6 to treat metastatic colorectal cancer

Trial purpose

The purpose of this trial was to learn about the safety and effects of PDR001 when given together with other commonly prescribed cancer treatments for MSS colorectal cancer. The main questions the researchers wanted to answer in this trial were:

- What medical problems did the participant have during the trial?
- Could PDR001 combined with other commonly prescribed cancer treatments stop MSS colorectal cancer from growing or spreading?

How long was this trial?

This trial started in September 2017 and ended in January 2018.

The sponsor decided to end this trial early. The decision to end the trial was not related to safety or how well PDR001 could have worked to treat MSS colorectal cancer.

When the trial ended, the researchers collected information on the trial treatment and created a report of the trial results. This summary is based on that report.

Who was in this trial?

The researchers designed this trial to include up to 92 men and women with metastatic MSS colorectal cancer. When the sponsor decided to end the trial early, only 1 participant had begun this trial. The participant could continue in the trial, but no other participants could join.

The participant was a 66 years old male and identified his race (ethnicity) as Caucasian (White). The participant took part at a trial site in the United Kingdom.

What kind of trial was this?

This was an open-label trial, which means that the participant and clinical trial team knew what treatment the participant got.

What happened during this trial?

During screening

Up to 4 weeks before treatment, trial doctors checked the participant's tumors and overall health to make sure he could be in this clinical trial. After 1 participant joined the trial, the sponsor decided to stop recruiting participants.

During treatment

The participant received each trial treatment through a vein as an intravenous (IV) infusion. Each treatment cycle lasted 4 weeks and included:

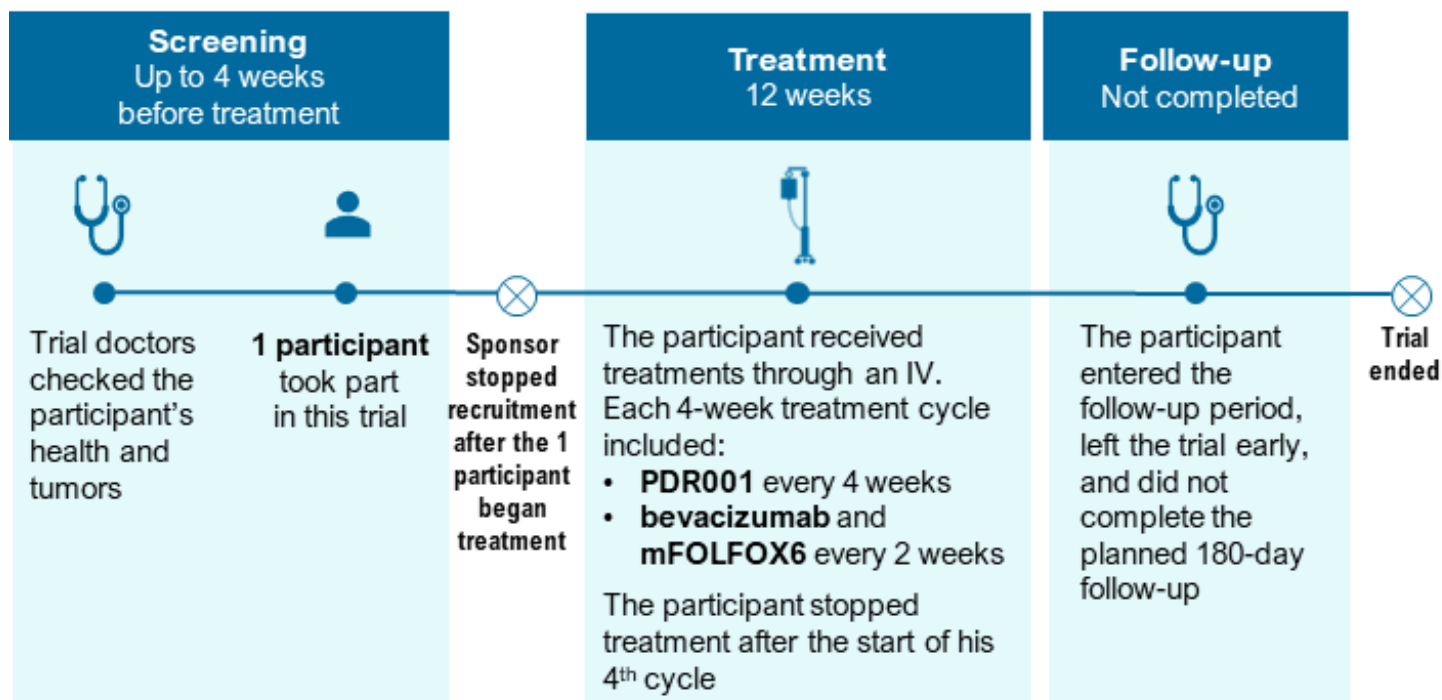
- **PDR001**, given every 4 weeks
- **bevacizumab**, given every 2 weeks
- **mFOLFOX6**, given every 2 weeks

Trial doctors checked the participant's health throughout the trial. During the participant's trial treatment, his MSS colorectal cancer got worse, and he decided to leave the trial early. He had completed 3 treatment cycles and had started a 4th treatment cycle.

During follow-up

The participant left the trial early and did not complete the planned 180-day follow-up. Since there were no other participants, the trial ended when he left.

How this trial was done:



What were the main results of this trial?

This is a summary of the overall results for this trial. More details on the results can be found on the websites listed at the end of this summary.

What medical problems did the participant have during the trial?

Medical problems that happen in clinical trials are called “**adverse events**”. An adverse event is an unwanted sign or symptom that participants have during a trial. An adverse event is considered “**serious**” when it is life-threatening, causes lasting problems, or the participant needs hospital care. These problems may or may not be caused by the trial drug.

A lot of research is needed to know whether a drug causes an adverse event. During a trial, all adverse events are recorded, whether or not they are thought to be caused by the trial drug. So, when new drugs are being studied, researchers keep track of all adverse events the participants have.

This section is a summary of the adverse events that happened during and after treatment. The websites listed at the end of this summary have more information about the adverse events that happened in this trial.

What were the serious adverse events?

A serious adverse event is when the adverse event is life-threatening, causes lasting problems, or the participant needs hospital care. These problems may or may not be caused by the trial drug. During this trial, the participant had 2 serious adverse events:

- Fever with a low number of white blood cells (febrile neutropenia)
- Fever (pyrexia)

The participant did not die during the clinical trial.

What were the most common non-serious adverse events?

The most common non-serious adverse events that happened to the participant were:

- Feeling tired (fatigue)
- Throwing up (vomiting)
- Feeling less hungry (decreased appetite)

The participant had other adverse events that happened less often.

Could PDR001 combined with other commonly prescribed cancer treatments stop MSS colorectal cancer from growing or spreading?

Because the trial ended early and had only 1 participant, the clinical trial team was unable to learn if PDR001 combined with other cancer treatments could stop MSS colorectal cancer from growing or spreading.

How has this trial helped?

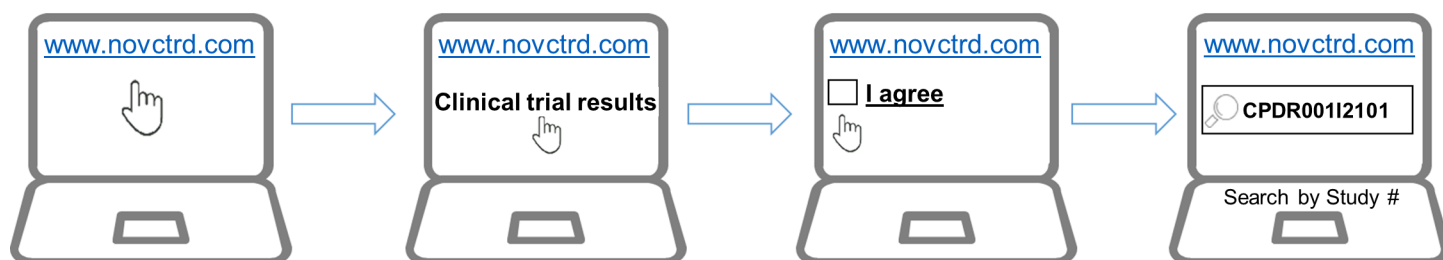
Because this trial ended early and had only 1 participant, the clinical trial team did not collect enough data to learn about the safety of PDR001 combined with the other cancer treatments. They were also unable to learn if this combination of treatments could stop MSS colorectal cancer from growing or spreading.

Please remember, this summary only shows the results of one clinical trial. Other clinical trials may have different results. Researchers and health authorities look at the results of many clinical trials to understand which drugs work and if they are safe. It takes many people in multiple clinical trials around the world to advance medical science and healthcare.

If more clinical trials are planned, they will appear on the public websites below. When there, search for PDR001, or spartalizumab.

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 on the Novartis Clinical Trial Results website (www.novctrd.com).



You can find more information about this trial on this website:

- www.clinicaltrials.gov. Use the NCT identifier 03176264 in the search field.

Full clinical trial title: A Phase Ib Study of PDR001 in Combination With Bevacizumab and mFOLFOX6 as First Line Therapy in Patients With Metastatic MSS Colorectal Cancer

Thank you

We thank the participant for taking part in this trial. Clinical trial participants belong to a large community of people around the world. The participant helped researchers answer important health questions and test new medical treatments.



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

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www.novartisclinicaltrials.com