Who sponsored this study?

Tesaro, a GSK company

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A study to evaluate the effects and safety of niraparib when given in combination with dostarlimab in participants with platinum-resistant ovarian cancer

GSK would like to thank all those who took part in this clinical study. We think it is important that you know the study results. We hope it helps you understand and feel proud about your important role in medical research.

General information about the clinical study

When and where was this study done?

The study started in October 2019 and ended in January 2022. All the study sites were in the United States. This study ended earlier than originally planned as the researchers found that very few participants responded to the study medicines.

Which medicines were studied?

Niraparib and dostarlimab are the two medicines that were studied.

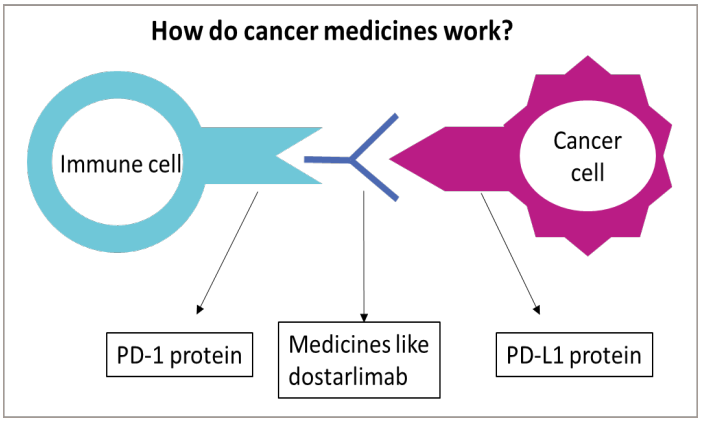
Niraparib
It is a medicine that can cause cancer cells to die. This may slow down the growth or return of the cancer.

Dostarlimab
It is a medicine that uses the body's own immune system to treat cancer

What was the main reason for this study?

Ovarian cancer is a type of cancer that starts in the ovaries. Advanced stage ovarian cancer is a cancer that starts in ovaries and has spread to other organs.

Immune cells have a type of protein on their surface called programmed cell death 1 (PD-1). Cancer medicines attach to this protein and may help the immune system attack and destroy the cancer cells. Some ovarian cancer cells have a type of protein on their surface called programmed cell death ligand 1 (PD-L1). These are called PD-L1 positive cancers.



Participants with advanced stage ovarian cancer who had previously been treated with cancer medicines called bevacizumab and platinum-based chemotherapy took part in this study. The participants' cancer could be PD-L1 positive (with the PD-L1 protein) or PD-L1 negative (without the PD-L1 protein).

In this study, researchers wanted to see if niraparib and dostarlimab when given together could shrink the tumours partially or completely. Researchers also assessed the safety of this medicine.

Who took part in this study?

Studies have a list of requirements for participants who can enter (inclusion criteria) and those who cannot enter (exclusion criteria). For this study, the main inclusion and exclusion criteria are listed below.

Women could take part in the study if they:

- Were at least 18 years old.
- Had advanced ovarian cancer with known resistance (medicine no longer works) to platinum-based therapy.
- Had previously received platinum-based therapy and other cancer medicines such as bevacizumab.
- Were capable of self-care as determined by a scoring scale before starting the study.

Women were excluded from the study if they had:

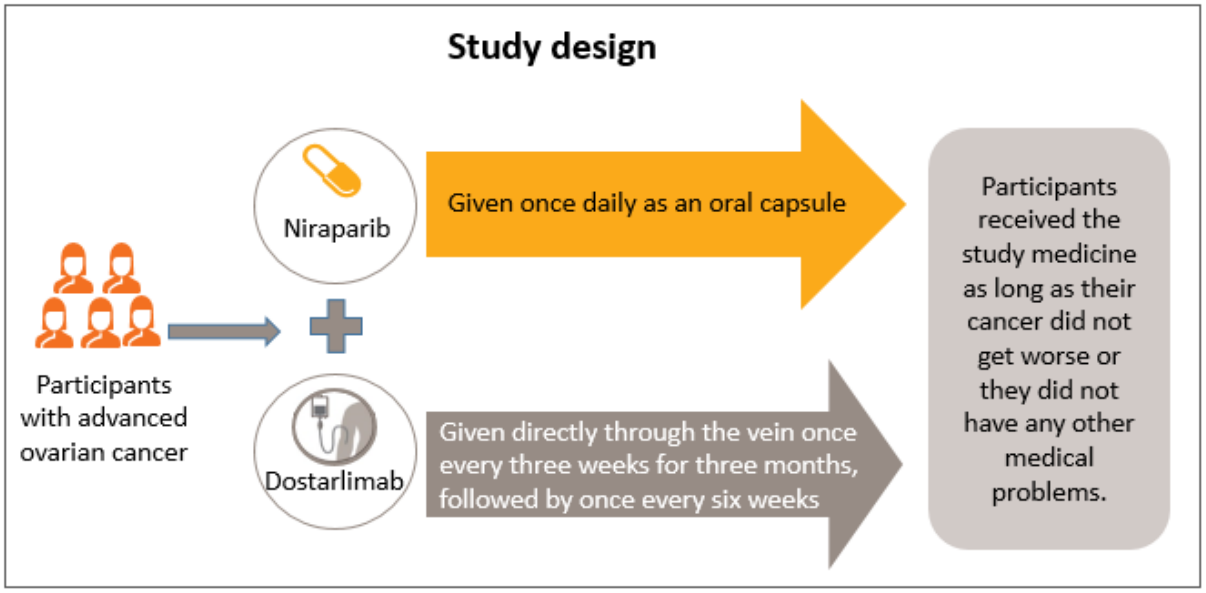
- Worsening of cancer within 3 months after receiving platinum-based therapy.
- Received a medicine similar to niraparib before starting the study.
- Any major surgery within one month of study start.
- Known liver infection.

It was planned to include approximately 150 participants in the study. At the time of early study termination, 41 participants had received the combination of niraparib and dostarlimab during the study. The average age of the participants was 63 years. The age range of the participants was from 35 to 77 years.

How was the study done?

This is an open-label study, which means that the participants and their study doctor knew which treatment the participant received.

As shown in the study design figure below, from Day 1, all participants received niraparib and dostarlimab.



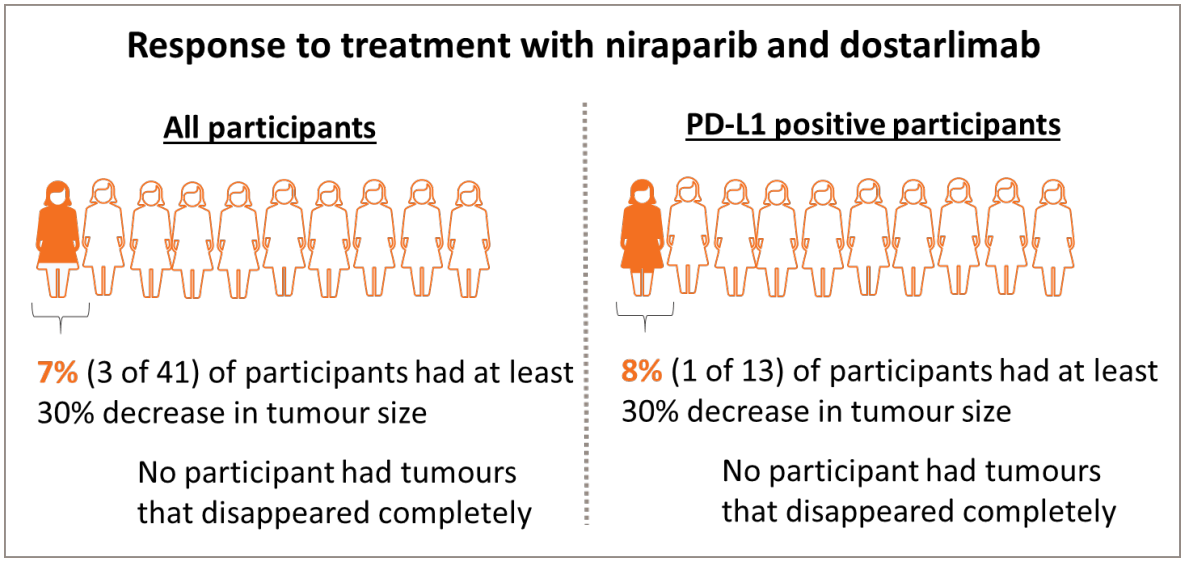
What were the main results of the study?

Study doctors assessed each participant's cancer using physical exams, scans, and blood tests.

Researchers measured the percentage of participants who had tumours that completely disappeared or became at least 30% smaller after starting the treatment. This is called objective response rate (ORR).

How many participants had tumours that completely disappeared or became at least 30% smaller after starting the treatment?

These results were studied in all participants (41 participants) and in participants with PD-L1 positive ovarian tumours (13 participants) as presented below.



What were the side effects?

Unwanted medical problems (adverse events) can happen to people when they receive a study medicine. Study doctors record these events.

In this summary, **side effects** refer to those events that the study doctor thinks may have been caused by the study medicine. The side effects in this summary may be different to those in the Informed Consent or other documents related to the study medicine.

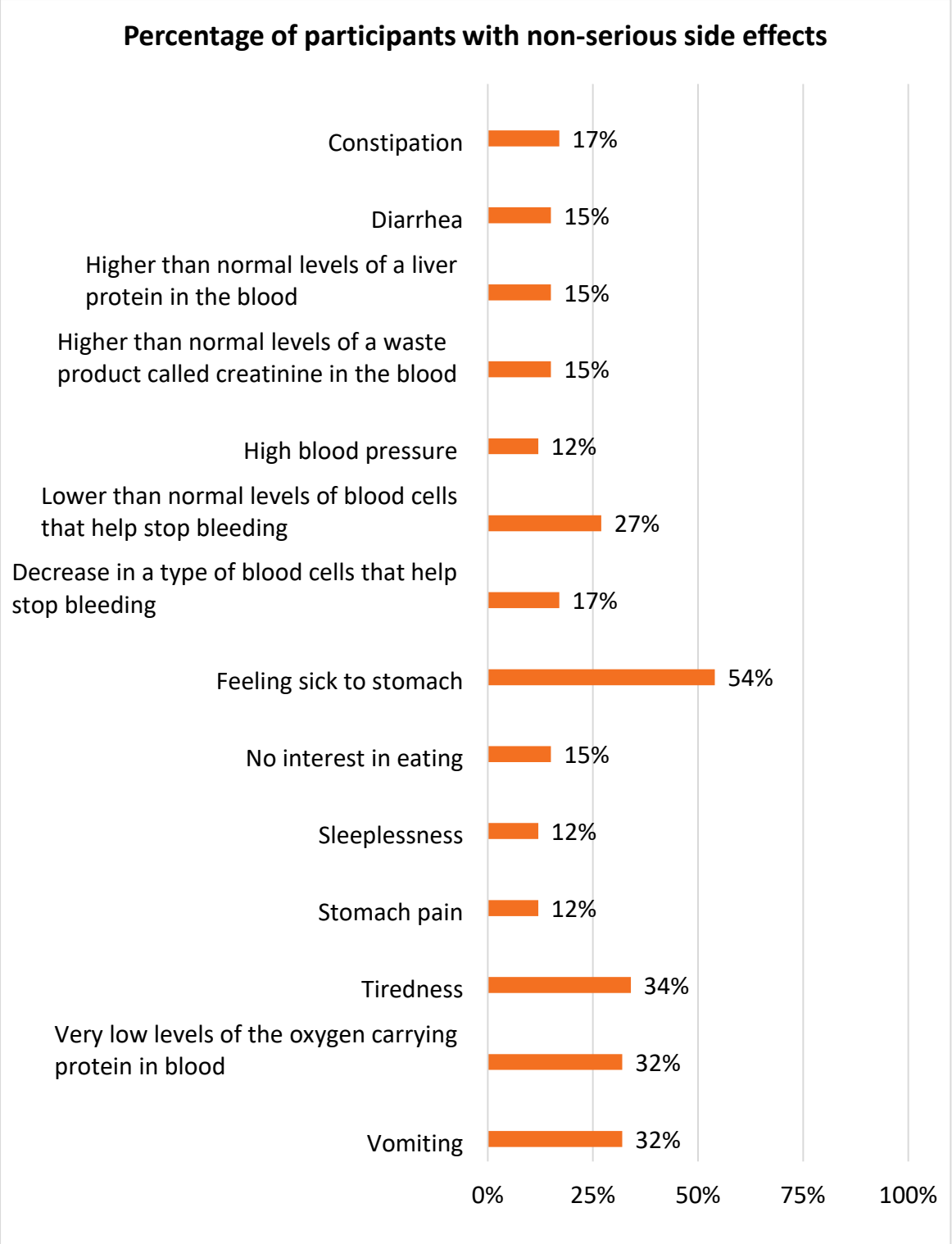
A summary of all events reported in this study may be found in the clinical results summary.

What were the serious side effects?

Serious side effects were reported by nine participants (22%). The only serious side effect reported by two or more participants was decrease in a type of blood cells that help stop bleeding, in three participants (7%). No fatal serious side effects were reported by participants in the study.

What were the non-serious side effects?

Non-serious side effects were reported by 39 participants (95%). The non-serious side effects reported by 10% or more of participants are shown below.



How has this study helped participants and researchers?

Researchers concluded that the effect of niraparib when given in combination with dostarlimab in causing tumour shrinkage in participants with advanced ovarian cancer and those with PD-L1 positive ovarian cancer was small. The side effects reported in this study were as expected.

Are there any plans for further studies?

Some studies of niraparib and dostarlimab in participants with ovarian cancer have been completed. Some GSK-sponsored studies are ongoing or planned.

Where can I find more information about this study?

Full title of this study: A phase 2 open-label, single-arm study to evaluate the efficacy and safety of the combination of niraparib and dostarlimab (TSR-042) in patients with platinum-resistant ovarian cancer (MOONSTONE).

Clinical studies have unique study numbers. The unique study number associated with this study is shown below with an internet link to the scientific summary.

Organisation (Website)	Study Identifier
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	NCT03955471[1]

The scientific summary includes more details about the requirements for study enrolment, the study visit schedule, results from other endpoints, and more detailed information about adverse events.

Your doctor can help you understand more about this study and the results. You should not make changes to your care based on the results of this or any single study.

We would like to **thank the participants** who contributed to this study. The results of this study will help answer scientific questions about treating participants with ovarian cancer.

The content for this document was finalised by GSK on 12 July 2022. The information in this summary does not include additional information available after this date.

[1] https://clinicaltrials.gov/ct2/show/NCT03955471