Who sponsored this study?
Tesaro, a GSK company

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A study to assess the effects of niraparib when given along with pembrolizumab in participants with advanced breast cancer and advanced 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

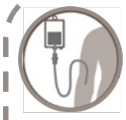
When and where was this study done?

The study started in April 2016 and ended in September 2021. All the study sites were in the United States.

Which medicines were studied?

The two medicines studied were niraparib and pembrolizumab.

Niraparib
It is a medicine that prevents cancer cells from repairing themselves. This may slow down the growth or return of the cancer.



Pembrolizumab
It is a medicine that uses the body's own immune system to treat cancer. It is approved in several countries to treat many types of cancer.

What was the main reason for this study?

Breast cancer starts in the lobes of the breast. Some breast cancer cells do not have certain proteins like estrogen, progesterone, and human epidermal growth factor receptor 2 (HER2) on their surface. Such breast cancers are called triple-negative breast cancers (TNBC).

Ovarian cancer generally starts in the ovaries. Both breast and ovarian cancers sometimes spread outside of where they started to other regions of the body, often referred to as advanced or recurrent cancer.

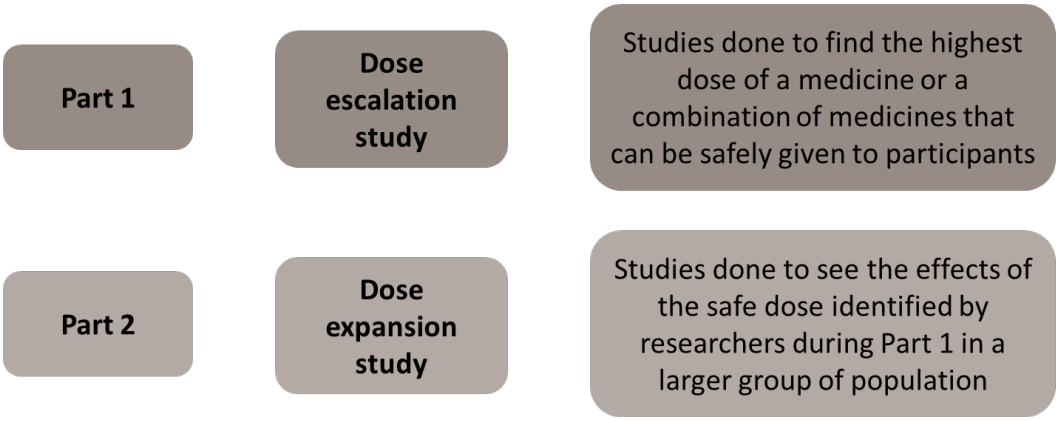
This study was conducted in participants who either had TNBC that had spread (later referred to as advanced breast cancer) or ovarian cancer that had returned (later referred to as ovarian cancer).

In this study, researchers looked if the combination of niraparib and pembrolizumab could be safe in participants with advanced breast cancer and ovarian cancer. Researchers also wanted to see if this combination could shrink the cancer cells either partially or completely.

How was the study done?

This was an open-label study where both the participants and researchers knew who was receiving which study medicine.

The study was conducted in 2 parts. Part 1 was the **dose escalation study** and Part 2 was the **dose expansion study**.



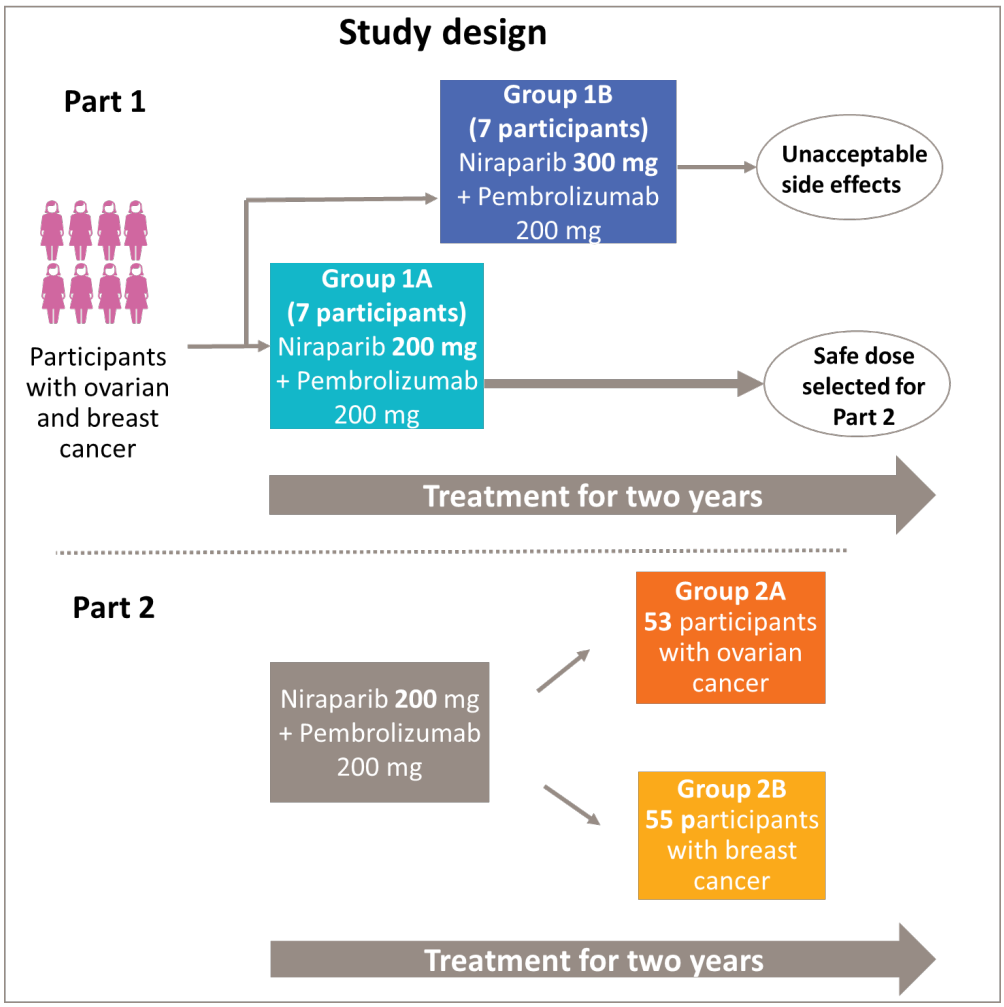
Part 1

In Part 1, researchers wanted to assess the safety of niraparib when given along with pembrolizumab. They wanted to identify a safe niraparib dose that could be used for Part 2. For this, the reseachers assessed the unacceptable side effects that occurred within three weeks of starting treatment. This is called dose-limiting toxicity (DLT).

Part 2

In Part 2, researchers wanted to assess the effects of the combination treatment of niraparib and pembrolizumab.

Participants in Part 1 and 2 received treatment as long as their cancer did not get worse, or have any other medical problems, or asked to be removed from the study.



Who took part in this study?

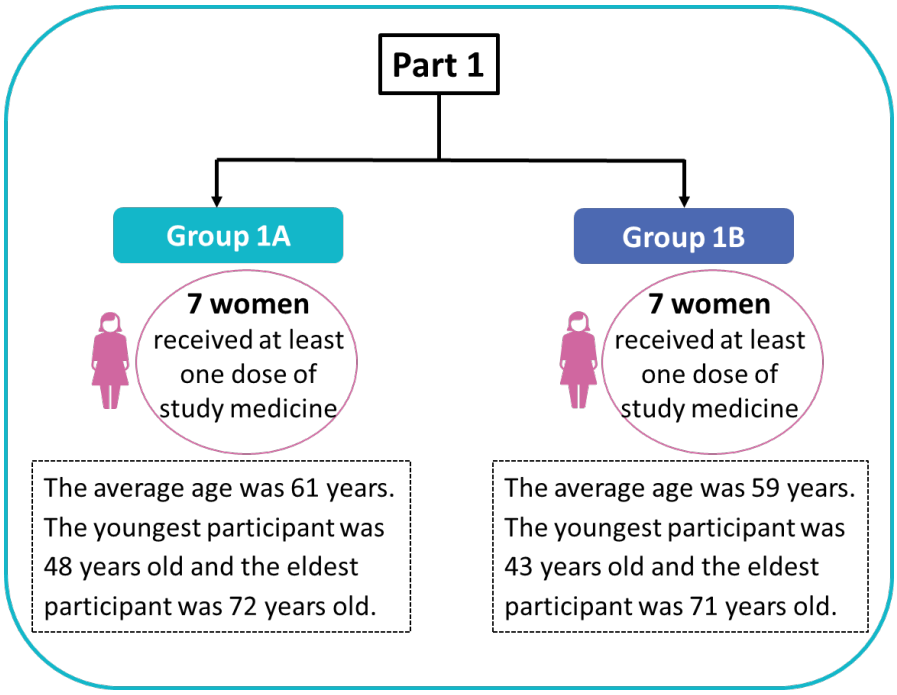
Studies have a list of requirements for participants who can enter (inclusion criteria) and those who cannot enter (exclusion criteria). For this study, the main inclusion and exclusion criteria are listed below.

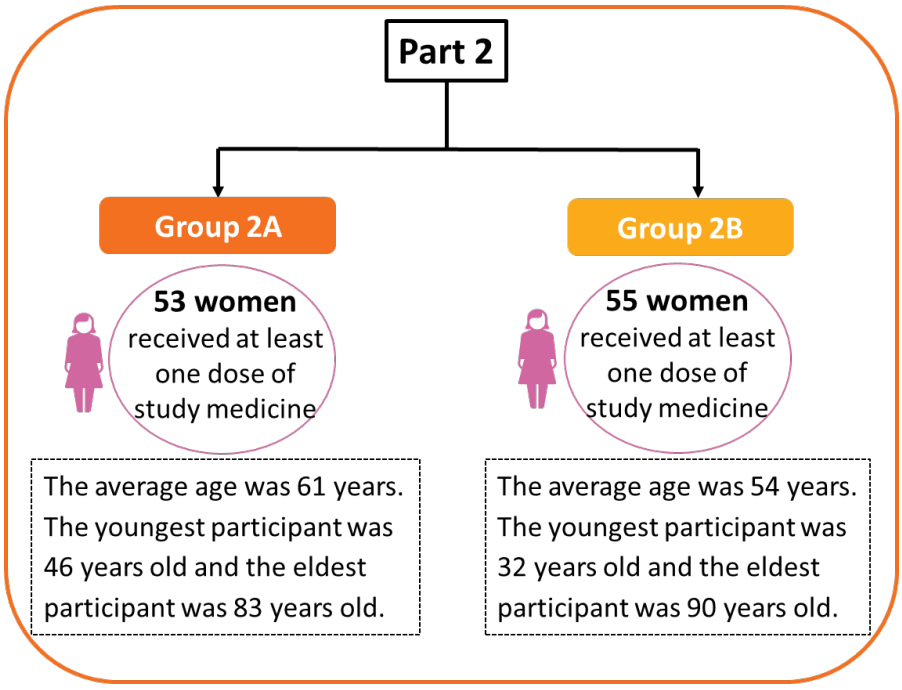
Men (in TNBC arm only) and women were included in the study if they:

- Were 18 years or older.
- Were either fully active or unable to do hard physical activity but able to do light housework or office work.
- Had measurable tumours.
- Were able to take medicines by mouth.

Men and women were excluded from the study if they had:

- Worsening of ovarian cancer (in women only) within 6 months of starting chemotherapy.
- Any other type of cancer.
- Received any other medicine similar to study medicines before study start.

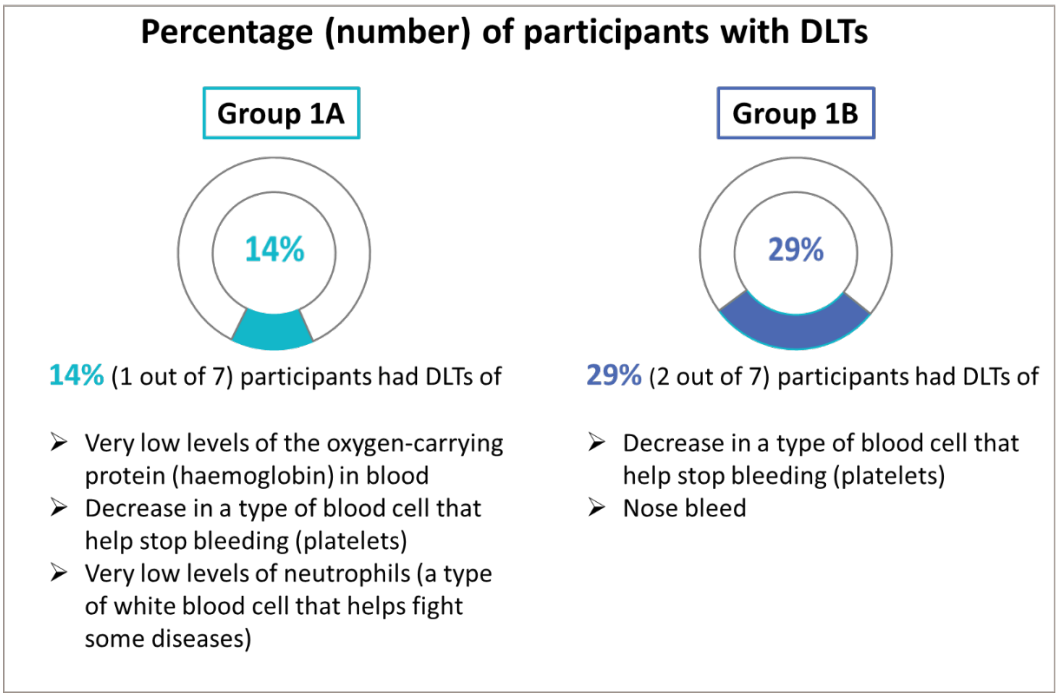




What were the main results of the study?

Part 1

What were the dose limiting toxicities (DLTs) observed?



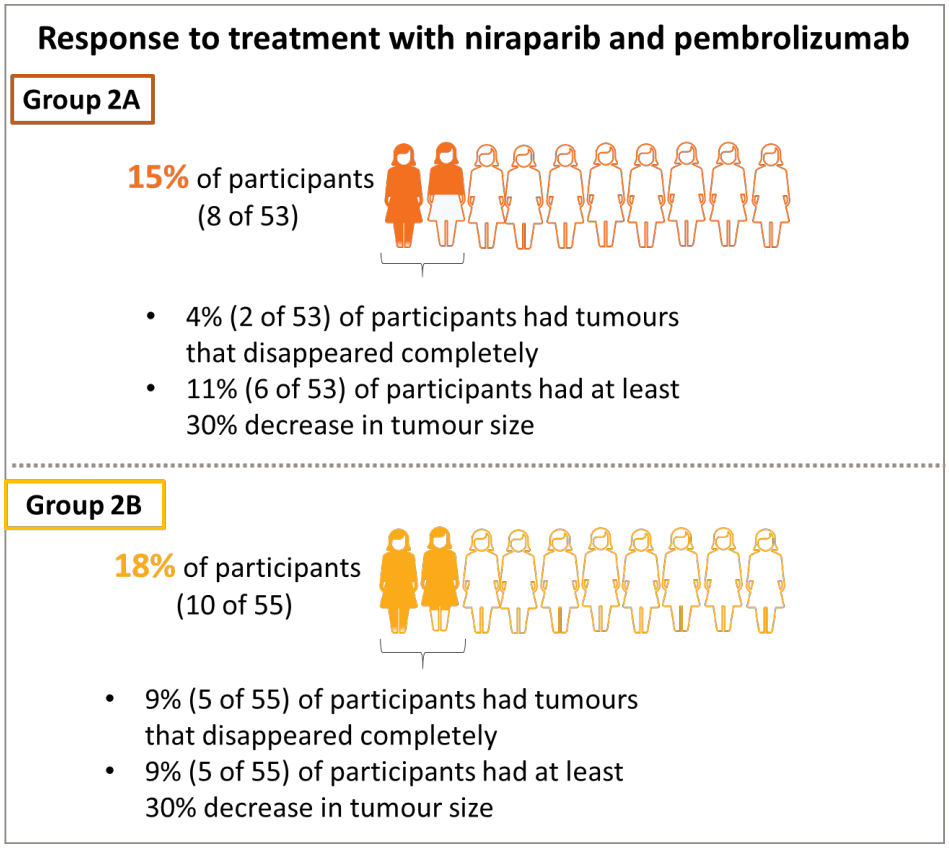
Researchers identified niraparib 200 mg + pembrolizumab 200 mg as the dose that could be safely given to the participants.

Part 2

Researchers assessed each participant's cancer using physical examinations, scans, and blood tests. Researchers measured the number of participants who had tumours that completely disappeared (complete response) or tumours that became at least 30% smaller after initiating treatment (partial response). This is together called as objective response rate (ORR).

How many participants had complete response or partial response?

These results were studied for participants in Group 2A (53 participants) and for participants in Group 2B (55 participants) as presented below.



What were the side effects?

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

In this summary, **side effects** refer to those events that the researchers think 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 at the end of this document.

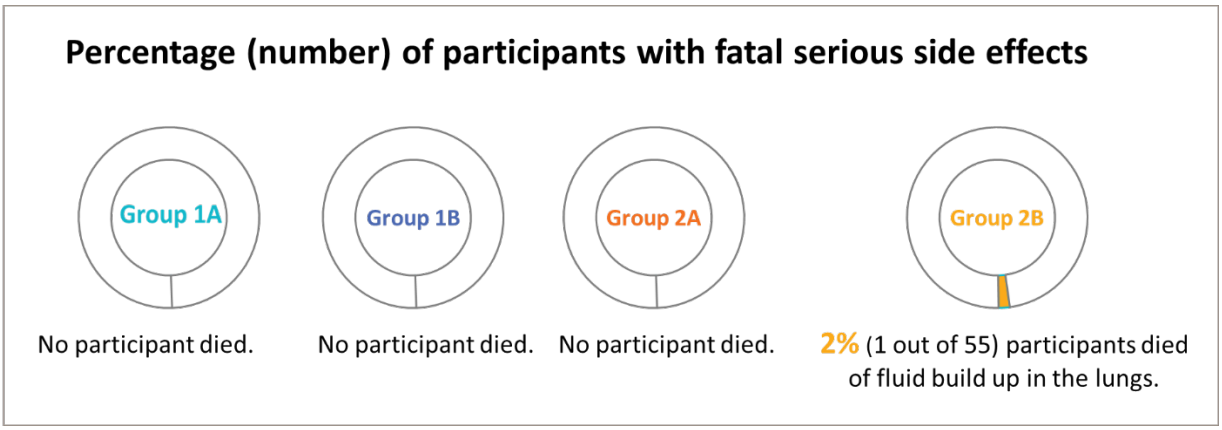
A total of 14 participants in Part 1 (7 participants in Group 1A and 7 participants in Group 1B) and 108 participants in Part 2 (53 participants in Group 2A and 55 participants in Group 2B) received at least one dose of study medicine. Side effects were reported for these participants.

What were the serious side effects?

The side effects were considered “serious” if they caused death, were life threatening, caused lasting problems, or required hospital care.

In this study, serious side effects were reported as fatal serious side effects that led to death and non-fatal serious side effects.

Fatal serious side effects:



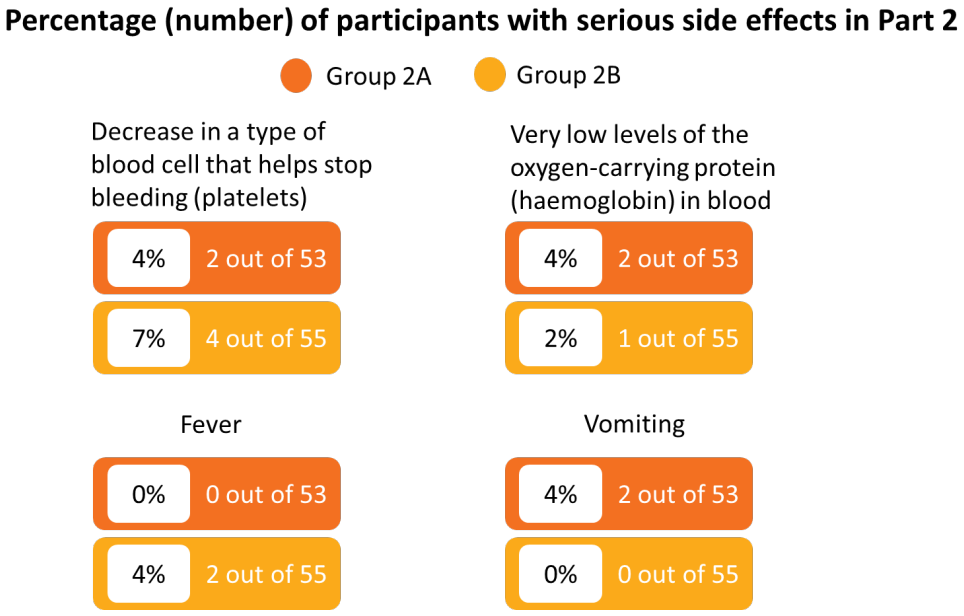
Non-fatal serious side effects:

Part 1:

Non-fatal serious side effects were reported by 2 participants (29%) in Group 1A and 4 participants (57%) in Group 1B. The non-fatal serious side effect reported by two or more participants was decrease in a type of blood cell that help stop bleeding in one participant (14%) in Group 1A and three participants (43%) in Group 1B.

Part 2:

Non-fatal serious side effects were reported by 12 participants (23%) in Group 2A and 11 participants (20%) in Group 2B. The non-fatal serious side effects reported by two or more participants in either group are shown below.

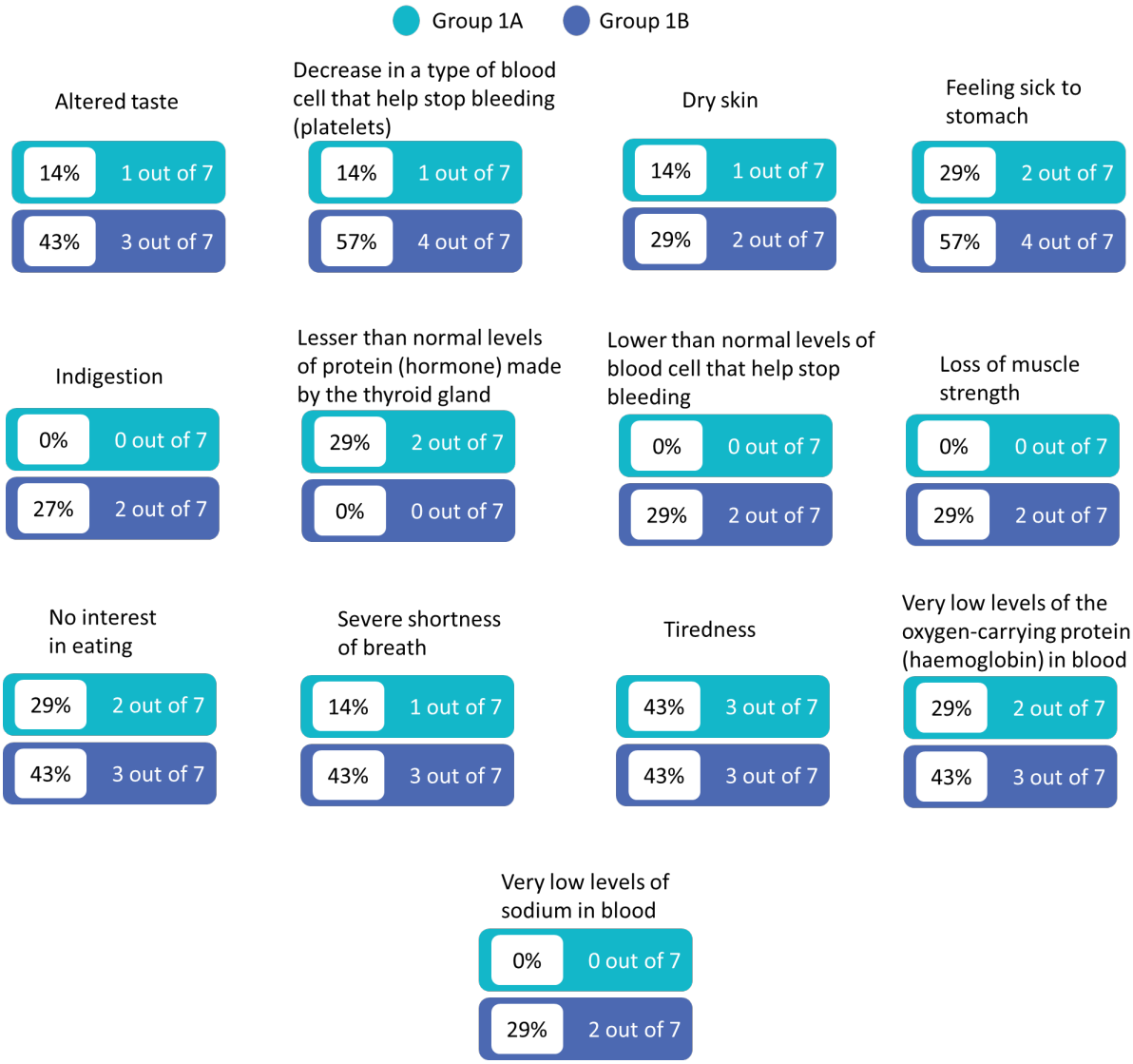


What were the non-serious side effects?

Part 1:

Non-serious side effects were reported by 6 participants (86%) in Group 1A and 7 participants (100%) in Group 1B. The non-serious side effects reported by two or more participants in either group are shown below.

Percentage (number) of participants with non-serious side effects in Part 1



Part 2:

Non-serious side effects were reported by 48 participants (91%) in Group 2A and 50 participants (91%) in Group 2B. The non-serious side effects reported by 10% of participants or more in either group are shown below.

Percentage (number) of participants with non-serious side effects in Part 2

How has this study helped participants and researchers?

Researchers concluded that participants with advanced breast cancer and ovarian cancer responded well to niraparib when given along with pembrolizumab. The study results provided a better understanding that niraparib along with pembrolizumab can be used to partially or completely shrink cancer cells. Researchers also found the combination treatment of niraparib along with pembrolizumab to be safe.

Are there any plans for further studies?

No studies of niraparib in combination with pembrolizumab in participants with advanced breast cancer and ovarian cancer are ongoing or planned, and one study has been completed.

Where can I find more information about this study?

Full title of this study: Phase 1/2 clinical study of niraparib in combination with pembrolizumab in patients with advanced or metastatic triple-negative breast cancer and in patients with recurrent ovarian cancer.

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)	NCT02657889[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 TNBC and ovarian cancer.

The content for this document was finalised by GSK on 26 August 2022. The information in this summary does not include additional information available after this date.

[1] https://clinicaltrials.gov/ct2/show/NCT02657889?term=213363