Who sponsored this study?

Tesaro, a GSK company

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A study to learn about the effects and safety of niraparib in participants with advanced ovarian cancer who have received three or four chemotherapy courses

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 was this study done?

The study started in April 2015 and ended in August 2021.

Which medicine was studied?

In this study, each participant received niraparib capsules (300 milligrams) once daily.

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

What was the main reason for this study?

Ovarian cancer is a type of cancer that starts in the ovaries, fallopian tubes, or the peritoneum in women. The inner lining of the abdomen is called peritoneum and the tubes that connect the ovaries to the uterus is called fallopian tubes. Advanced ovarian cancer is a cancer in the ovaries that has spread to other organs of the body.

Some people may have genetic changes called mutations in their cancer cells. These changes make it difficult for the cancer cells to repair by themselves when they get damaged. This reduced ability is called homologous recombination deficiency (HRD). Before the participants took part in the study, a genetic test of their cancer samples was done to find out whether the participants had a harmful breast cancer (BRCA) gene.

Participants with advanced HRD positive ovarian cancer with or without BRCA gene took part in the study. Participants also had received three or four chemotherapy courses and had responded to the platinum-based chemotherapy (partial or complete tumour shrinkage).

In this study, researchers wanted to see if niraparib could shrink the cancer cells partially or completely. Researchers also studied the safety of niraparib.

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 were included in the study if they:

- Were at least 18 years old.
- Were willing to undergo HRD testing.
- Had advanced ovarian cancer and have completed three or four chemotherapy treatments at least one month before starting the study medicine.
- Were either fully active or unable to do hard physical activity but able to do light house work or office work.

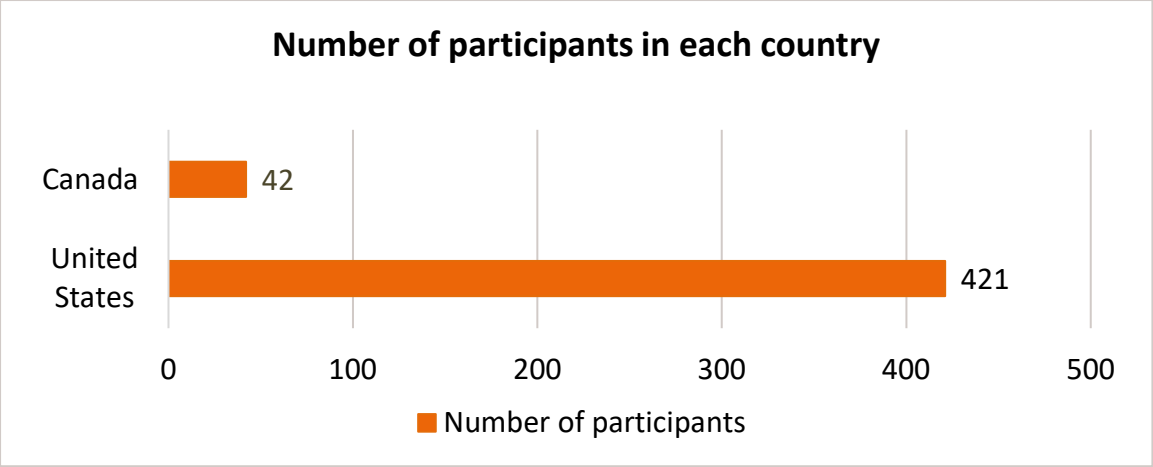
Women were excluded from the study if they had:

- Received radiotherapy treatment within one year before starting the study medicine.
- Received white blood cells or red blood cells directly through a vein (blood transfusion) within one month before receiving the study medicine.
- Any major surgery within three weeks before starting the study.
- Known liver infection.

Overall, 463 women took at least one dose of study medicine. The average age of the participants was 64 years. Participants age ranged from 29 to 91 years.

Where was this study done?

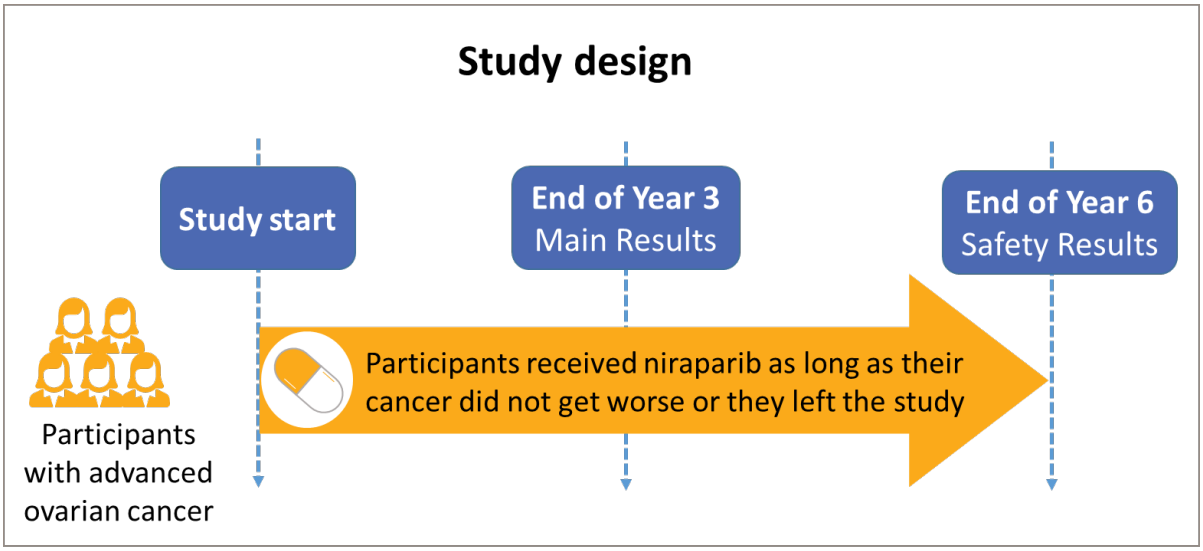
Study sites were in two countries.



How was the study done?

As shown in the study design figure below, participants received niraparib once daily.

The participants and their study doctor knew which treatment the participant received. This is called an open-label study.



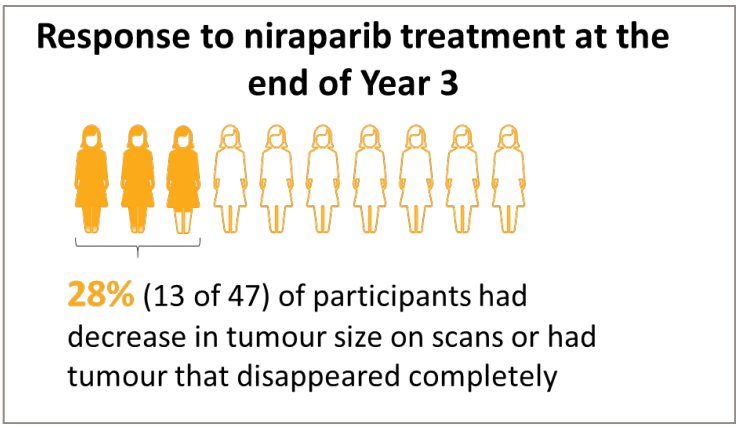
What were the main results of the study?

Study doctors assessed each participants' cancer using physical examinations, scans, and blood tests at study start and at the end of Year 3.

Researchers measured the number of participants who had tumours either completely disappeared or appeared smaller on scans after starting treatment. This is called objective response rate (ORR).

How many participants had tumours that completely disappeared or became smaller on scans after starting the treatment?

These results were available for 47 participants as shown in the figure below.



What were the side effects?

Unwanted medical problems (adverse events) can happen to people when they receive a 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 Form or other documents related to the study medicine.

A summary of all events reported in this study may be found in the link to the clinical trial results summary provided at the end of this document.

Side effects in this summary have been reported up to Year 6.

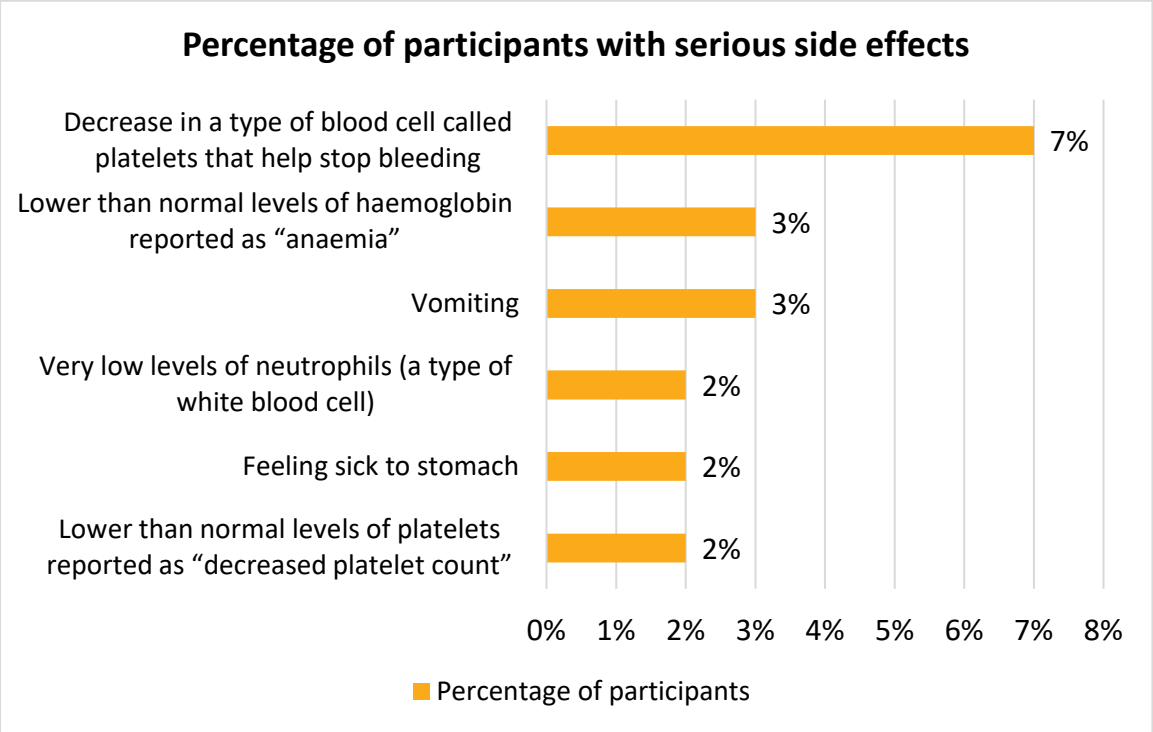
What were the serious side effects?

The side effects are considered "serious" if they cause death, are life threatening, cause lasting problems, or require 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.

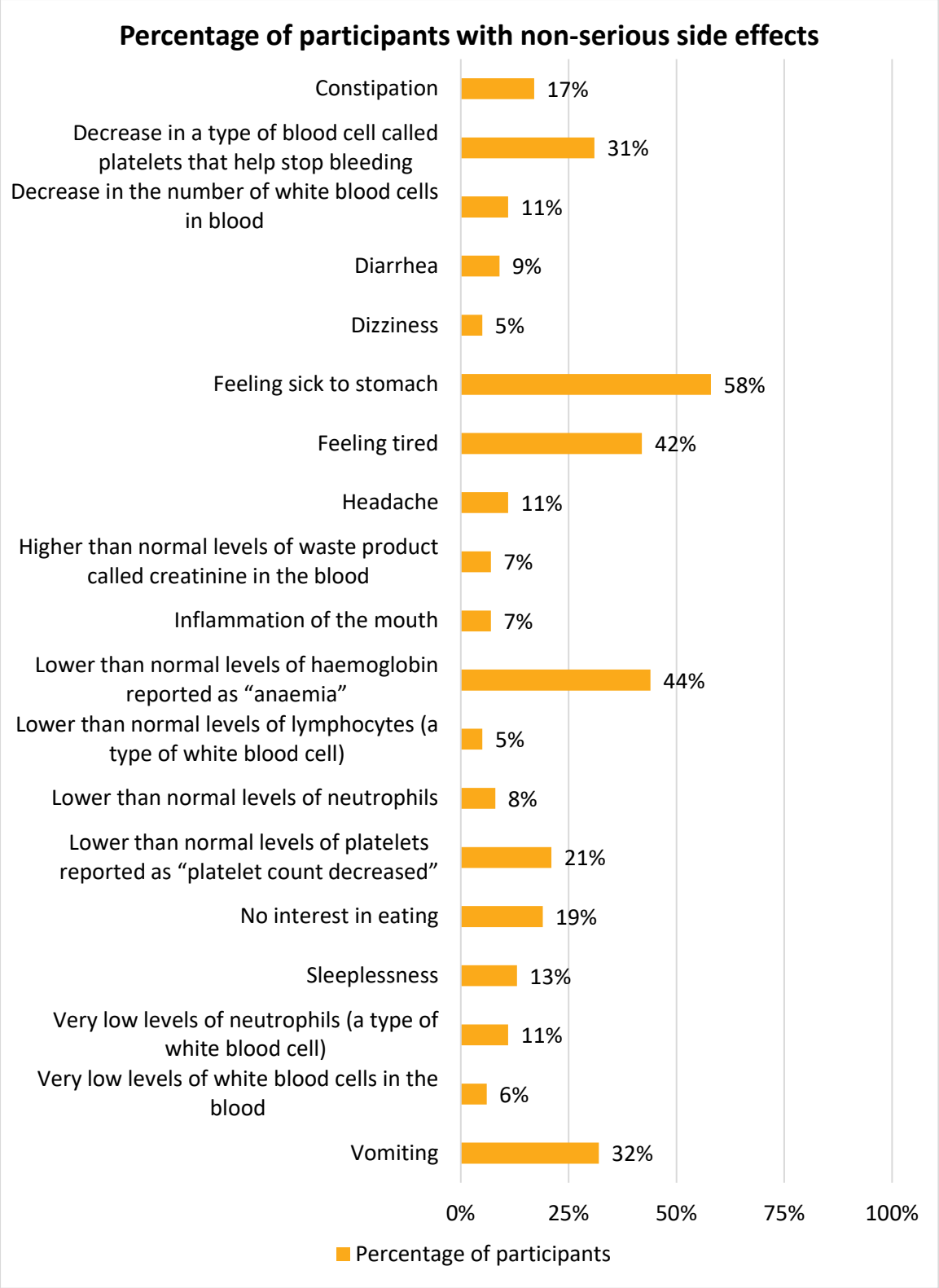
A fatal serious side effect of cancer that started in the blood (leukemia) was reported in one participant (less than 1%).

Non-fatal serious side effects were reported by 91 participants (20%). The non-fatal serious side effects reported by 1% or more of participants are shown below.



What were the non-serious side effects?

Non-serious side effects were reported by 440 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 made an observation that participants with advanced ovarian cancer responded well to niraparib treatment. The study results provided a better understanding

of how niraparib can be used to partially or completely shrink the ovarian cancer cells. The side effects reported in this study were as expected.

Are there any plans for further studies?

A few studies of niraparib in participants with ovarian cancer have been completed. Some 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 safety and efficacy of niraparib in patients with advanced, relapsed, high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received three or four previous chemotherapy regimens**.**

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

Organisation (Website)	Study Identifier
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	NCT02354586[1]

The clinical trial results 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 18 July 2022. The information in this summary does not include additional information available after this date.

[1] https://clinicaltrials.gov/ct2/show/NCT02354586?term=213360