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Plain Language Summary of Publication

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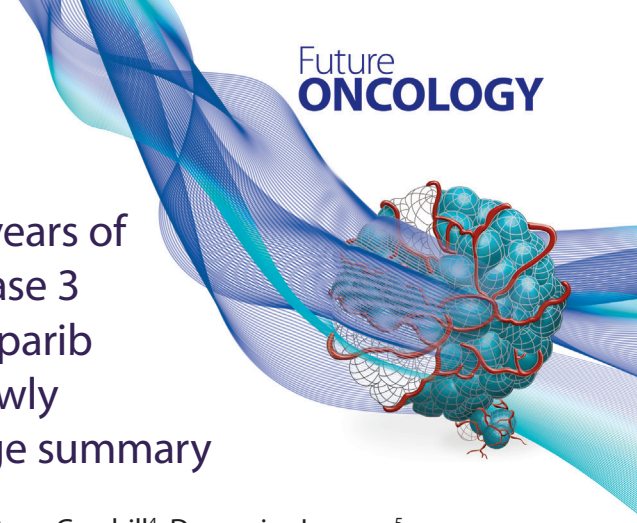

Progression-free survival and safety at 3.5 years of follow-up: results from the randomized phase 3 PRIMA/ENGOT-OV26/GOG-3012 trial of niraparib maintenance treatment in patients with newly diagnosed ovarian cancer – a plain language summary

Antonio González-Martín[1], Bhavana Pothuri[2], Ignace Vergote[3], Whitney Graybill[4], Domenica Lorusso[5], Colleen C McCormick[6], Gilles Freyer[7], Floor Backes[8], Florian Heitz[9], Andrés Redondo[10], Richard G Moore[11], Christof Vulsteke[12], Roisin E O'Cearbhaill[13], Izabela A Malinowska[14], Luda Shtessel[14], Natalie Compton[14], Mansoor R Mirza[15] and Bradley J Monk[16]

Full affiliation information can be found at the end of this plain language summary.

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Summary

What is this summary about?

This PLSP provides a short summary of an original scientific article that presented results from the PRIMA study after 3.5 years of **follow-up time**. The original article was published in the *European Journal of Cancer* in 2023.

The PRIMA study included adult patients with newly diagnosed advanced high-risk ovarian cancer whose tumors shrunk or became undetectable after treatment with **chemotherapy** with or without surgery. The PRIMA study evaluated how well the drug niraparib, also known as Zejula, worked at delaying or preventing ovarian cancer from coming back (recurring) or getting worse (progressing) compared with **placebo** (a substance with no effects that a doctor gives to a patient instead of a drug). The first results from the PRIMA study were published in 2019, when patients had participated in the PRIMA study for about 1.2 years.

The article this PLSP is based on reports longer-term data from the PRIMA study, when patients had participated in the PRIMA study for about 3.5 years. Patients were monitored (or followed) for a longer time to understand how well niraparib continued to work and to evaluate whether the safety of niraparib changed with additional time being monitored.

What were the results?

Patients who took niraparib had more time before their cancer came back or got worse than patients who took placebo. In terms of safety, no new types of **side effects** with niraparib treatment were observed with additional time being monitored as part of the PRIMA study.

What do the results mean?

These results support that niraparib remains an important treatment option to help delay the cancer from coming back or getting worse in patients with newly diagnosed advanced ovarian cancer that responded to initial treatment.

How to say (double click sound icon to play sound)...

- **Niraparib:** nih-RAP-uh-rib
- **Homologous:** huh-MAA-luh-guhs
- **Recombination:** ree-kaam-buh-NAY-shn
- ***BRCA*:** brah-KUH

Follow-up time: The amount of time a patient is monitored as part of a clinical study. Follow-up includes the time when patients are actively being treated and extends past the end of treatment to when patients are monitored for long-term outcomes. For clinical studies of cancer, long-term outcomes can include time to the next treatment, overall survival, and safety.

Chemotherapy: Prescribed drugs given alone or in combination that are used to kill fast-growing cancer cells.

Placebo: A substance with no effects that a doctor gives to a patient instead of a drug. In the PRIMA study, placebo was given to some patients instead of niraparib.

Side effect: Any unintended, unpleasant, or harmful symptom a patient develops when taking a drug. Side effects may be directly related to the medications patients are taking, while others may occur at random times during treatment. They can vary in severity from mild to life-threatening.

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Where can I find the original article on which this summary is based?

The original article is titled "Progression-free survival and safety at 3.5 years of follow-up: results from the randomised phase 3 PRIMA/ENGOT-OV26/GOG-3012 trial of niraparib maintenance treatment in patients with newly diagnosed ovarian cancer" and is free to access at: https://www.ejcancer.com/article/S0959-8049(23)00225-3/fulltext

What is a plain language summary of publication?

A plain language summary of publication (PLSP) is a summary of an original scientific article written in common, everyday language for general audiences. In the field of medicine, scientific journal articles are written by physicians and other medical professionals to communicate important research findings within their area of practice (for example, oncology). These articles contain technical language that may be difficult to understand without medical training. The purpose of this PLSP is to help patients and their caregivers understand the results from the original article in nontechnical, accessible language, enabling patients to make informed decisions about their care. This PLSP may also be useful for health care professionals specialized in other areas of care who are interested in the results.

What is the purpose of this PLSP?

The purpose of this PLSP is to help you to understand the findings from recent research.

Niraparib (Zejula) is approved to treat the condition under study, which is discussed in this summary. Approval varies by country; please check with your local provider for more details. The results of this study may differ from those of other studies. Health professionals should make treatment decisions based on all available evidence, not on the results of a single study. This summary reports the results of an unplanned long-term analysis of the study. The study described is still ongoing; therefore, the final outcomes of this study may differ from the outcomes described in this summary.

Who sponsored the study?

This study was **sponsored** by GSK (Waltham, MA, USA).

Sponsor: A sponsor is a company or organization that oversees and pays for a clinical research study. The sponsor also collects and analyzes the information that was generated during the study.

Who should read this PLSP?

This summary may be helpful for patients with newly diagnosed advanced ovarian cancer, their family members, or their caregivers. It may also be helpful for patient advocates and other healthcare professionals who have an interest in ovarian cancer.

What questions does this PLSP answer?

Through 3.5 years of the PRIMA study:

1	Did niraparib continue to delay the cancer from coming back or getting worse?	**Yes** Patients taking niraparib had a significantly longer time without the cancer coming back or getting worse than patients taking placebo.
2	Did the types of side effects associated with niraparib change with additional time being monitored?	**No** Patients taking niraparib did not experience any new types of side effects after being monitored for a longer time.

What is ovarian cancer, and how is it treated?

Ovarian cancer is cancer that originates, or starts, in the ovaries, **peritoneum**, or **fallopian tubes**. If ovarian cancer is not found and treated early, the cancer continues to grow and may spread to other organs in the abdomen or throughout the body. Because ovarian cancer causes few symptoms early on in the disease and is difficult to detect, many patients already have advanced (late stage or severe) disease when they are first diagnosed.

Peritoneum: The thin layer of cells that lines the abdominal (belly) cavity.
Fallopian tubes: The hollow tube structures that connect the ovaries (where eggs are made) and the uterus (where a fertilized egg can develop into a fetus).

Patients with advanced ovarian cancer are typically treated with surgery and chemotherapy. The surgery removes as much of the cancer as possible, and the chemotherapy is used to try to kill any remaining cancer cells. Most patients receive **platinum-based chemotherapy**.

Platinum-based chemotherapy: A type of chemotherapy that uses drugs containing platinum. The drugs kill cancer cells and are thought to work because the platinum molecules bind to and damage the **DNA** in cancer cells.
DNA: The molecule that carries genetic information for an organism.

Patients with advanced ovarian cancer are at a high risk for the cancer coming back and death even if their diease responds to initial treatment. To help address this, patients with advanced ovarian cancer may be treated with maintenance therapies, which are given after surgery and chemotherapy. The goal of maintenance therapy is to keep up, or maintain, the response from initial treatment (for example, tumor shrinkage or disappearance) and to prevent or delay the cancer from coming back or getting worse.

What drug was tested?

Niraparib was the medicine tested in the PRIMA study.

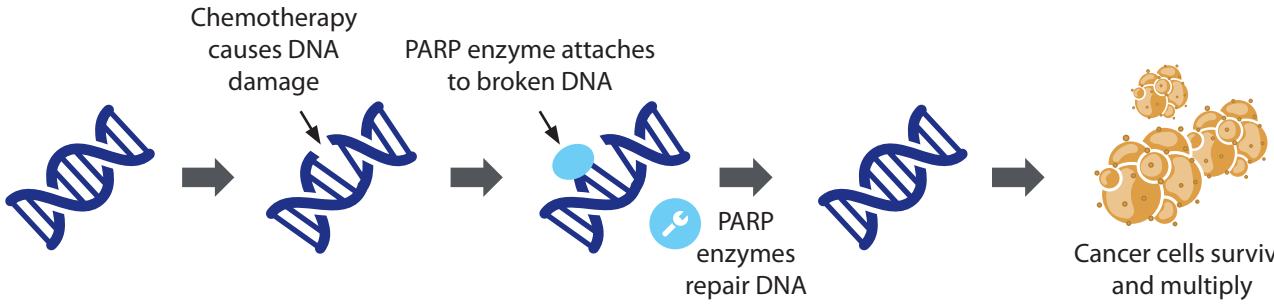
Niraparib is:
- a type of drug called a poly(ADP-ribose) polymerase inhibitor or **'PARP inhibitor'**.
- used as maintenance treatment in patients with advanced ovarian cancer that responded to chemotherapy.
- an oral medication, taken by mouth once daily.

PARP inhibitors: Anticancer drugs that work by blocking DNA repair and helping to kill cancer cells.

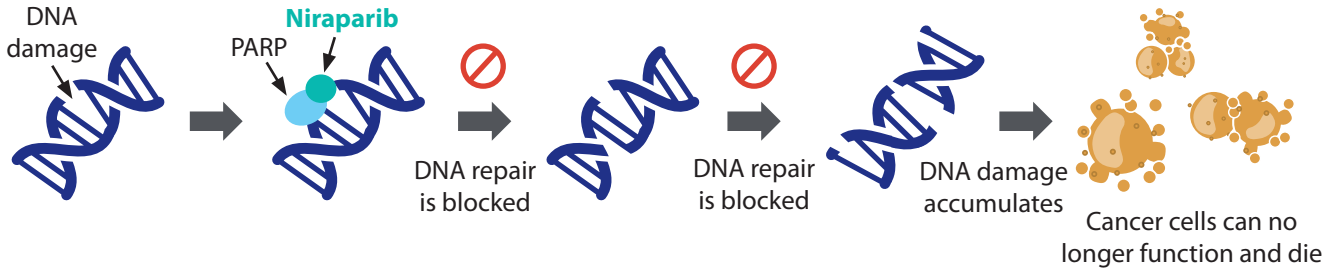
10.2217/fon-2023-0782

How does niraparib work?

Chemotherapy kills cancer cells by damaging their DNA. Cancer cells can use **PARP** enzymes to fix the DNA damage, preventing chemotherapy from killing them.



Niraparib attaches (binds) to the PARP enzyme and stops it from fixing damaged DNA. With niraparib blocking DNA repair, the DNA damage gets worse over time. The DNA damage eventually gets so severe that the cancer cells can no longer function and they die.



PARP inhibitors block DNA repair in all cells but may have an even greater effect in cells with specific DNA **mutations** that prevent DNA **repair by homologous recombination** (HR). Cells that cannot use HR are called **homologous recombination-deficient**, or HRd. PARP inhibitors may work better in HRd cells because it is harder for those cells to repair damaged DNA. Tumor samples collected during surgery can be tested for HRd mutations, which is ordered by oncologists, doctors who specialize in treating cancer. Patients with ***BRCA* gene** mutations have tumors that are HRd.

As such, niraparib may be a particularly good treatment option for some patients based on their tumor DNA-testing results.

Adapted from MR Mirza, A González-Martín, WS Graybill, et al. A plain language summary of publication of the efficacy and safety of individualized niraparib dosing based on baseline body weight and platelet count in the PRIMA/ENGOT-OV26/GOG-3012 trial. Future Oncol. 2023. doi: 10.2217/fon-2023-0755

PARPs: Enzymes that help to repair damaged DNA. Enzymes are molecules that can speed up chemical reactions in cells. Enzymes are not destroyed in the reaction and can be used over and over.
Mutation: A change in the DNA sequence of an organism. Mutations in genes can stop them from working properly.
Homologous recombination-deficient (HRd): Cells that cannot repair DNA using **homologous recombination repair**.
Homologous recombination repair: A method of DNA repair used to fix damaged or broken DNA.
***BRCA*:** The *BRCA1* and *BRCA2* genes are involved in DNA repair and play an important role in preventing cancer and slowing cancer growth. Cells with *BRCA* mutations cannot fix DNA using homologous recombination repair and are classified as HRd.
Gene: A short section of DNA. Many genes contain instructions to make different molecules that cells need to function.

What study are these results from?

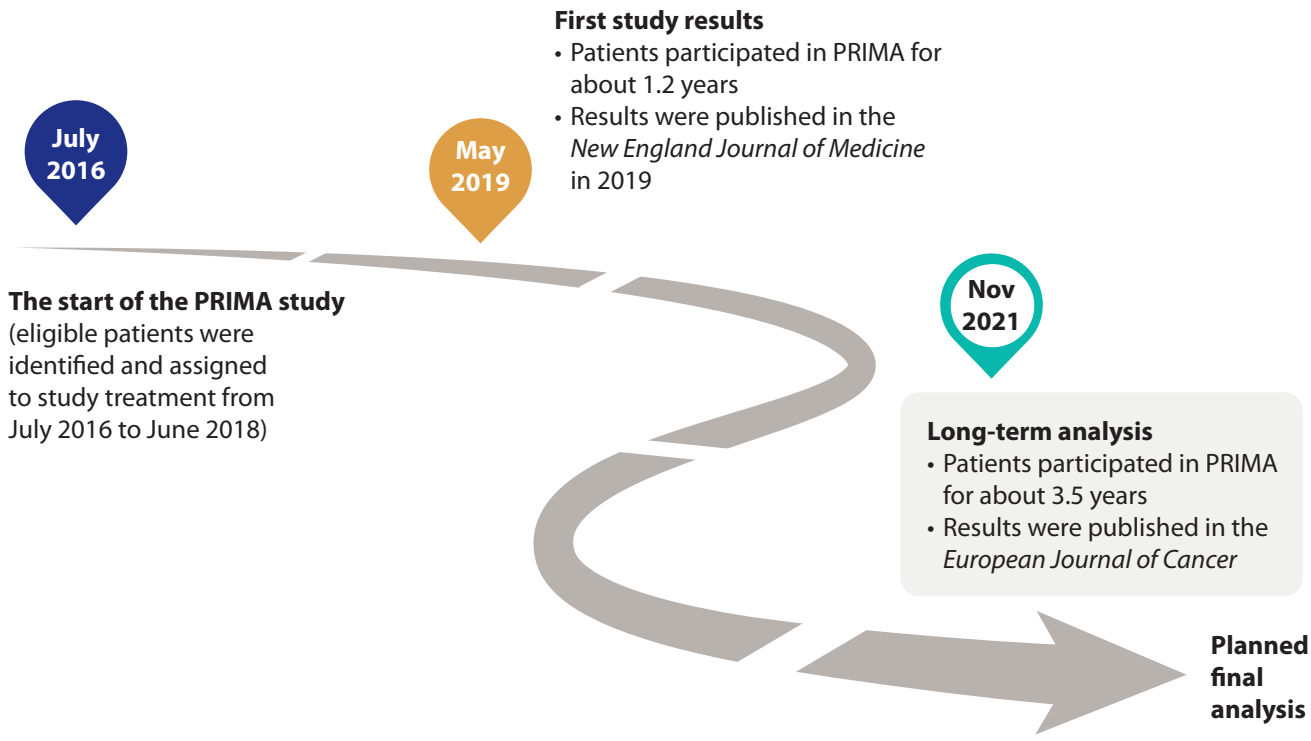
These results are from the PRIMA study. The PRIMA study was designed by researchers to evaluate whether patients with advanced ovarian cancer could benefit from niraparib maintenance treatment. In particular, researchers wanted to see whether patients treated with niraparib would live longer without the cancer coming back or getting worse.

To evaluate the benefit of niraparib maintenance therapy, the PRIMA study directly compared treatment with niraparib maintenance therapy to treatment with placebo (a substance with no effects that a doctor gives to a patient instead of a drug). To make sure one treatment wasn't favored over the other, the PRIMA study was both randomized and double-blinded. This means that patients were assigned to each treatment by chance (randomized) and that neither the patients nor the doctors overseeing PRIMA knew which treatments the patients received until all the data for the initial analysis were collected (double-blind).

When the PRIMA trial started, patients with advanced ovarian cancer typically did not receive additional treatment after initial chemotherapy treatment ended. Because no additional treatment was the standard of care, it was acceptable to compare maintenance treatment with niraparib to placebo (no active treatment) in the PRIMA study.

The first results from the PRIMA study were reported in 2019 and were published in the *New England Journal of Medicine*. The results showed that niraparib maintenance treatment significantly delayed the cancer from coming back or getting worse compared with placebo. The PRIMA study started in 2016 and is ongoing at the time of this publication. Results from different parts of the study have also been published in other articles.

PRIMA study timeline



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Why was this long-term analysis done?

In the 2019 article, patients had participated in the PRIMA study for about 1.2 years.

To understand what happened when the patients were monitored for a longer time, the 2023 article that this PLSP is based on evaluated the same patients after they had participated in the PRIMA study about 3.5 years. Depending on when patients began participating in the PRIMA study, they may have been followed for shorter or longer than 3.5 years.

Which patients participated in the PRIMA study?

The PRIMA study included adult patients with advanced ovarian cancer who were considered at high risk for the cancer getting worse or dying because of their clinical characteristics.

Patients were required to have:

Stage III or IV ovarian cancer at diagnosis

In stage III and IV ovarian cancer, cancer cells are present in one or both ovaries and are also found in the draining **lymph nodes** and/or other parts of the abdomen. In stage IV ovarian cancer, which is the most severe or advanced stage, cancer cells have spread outside the abdomen and can be found in distant sites like the brain or lungs.

In the PRIMA study, patients with stage III disease had to have tumors that could not be removed completely by surgery.

Lymph nodes: Small, rounded pieces of tissue that contain white blood cells that help fight infection. Lymph nodes exist throughout the body and are often associated with specific tissues or organs. Cancer often spreads to the lymph nodes closest to the original tumor, and the more lymph nodes that contain cancer cells, the more advanced (worse) the cancer.

A complete or partial response to initial platinum-based chemotherapy

In patients with a complete response to initial treatment, the tumors present at diagnosis disappear completely. In patients with a partial response to initial treatment, the tumors present at diagnosis shrink in size and no new tumors are found.

A tumor tissue sample taken for genetic testing

The tumor tissue was tested to determine whether tumors were homologous recombination-deficient (HRd) or **homologous recombination-proficient (HRp)**. Tumor samples were also tested for *BRCA* mutations as part of this process. Patients participated in the PRIMA study whatever their tumor tissue–testing results.

Homologous recombination-proficient (HRp): Cells that can repair DNA using homologous recombination repair.

What were the characteristics of patients in the PRIMA study?

487
Patients were selected by chance to be treated with niraparib

246
Patients were selected by chance to be treated with placebo

The median age was 62 years. Median is the middle value when all values are sorted from lowest to highest. Therefore, half of the patients were older than 62 years, and half of the patients were younger than 62 years

51% of all patients had tumors that were HRd (a total of 373 patients)
- Of the patients with HRd tumors, 60% had tumors with *BRCA* mutations (a total of 223 patients)

At the time of the analysis
(data were collected from the start of the study until November 2021)

Treatment duration longer than 3 years
- 21% of patients receiving niraparib
- 16% of patients receiving placebo

Still receiving study treatment
- 16% of patients receiving niraparib
- 11% of patients receiving placebo

What were the findings on delaying the cancer from coming back or getting worse?

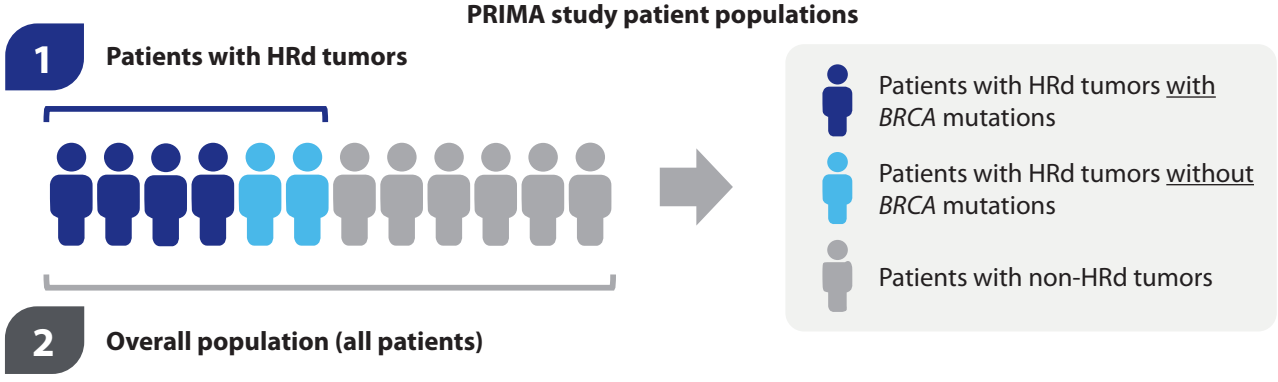
In the PRIMA study, how well niraparib worked was evaluated in 2 patient groups based on their tumor characteristics. The study plan, which directed how the study was performed, required that group 1 was analyzed first, followed by group 2.

Patient groups were determined based on tumor genetic testing results.

1 Patients with HRd tumors: this population included only patients with HRd tumors and was evaluated first

2 Overall population: this population included all patients no matter their HR status and was evaluated second

PRIMA study patient populations



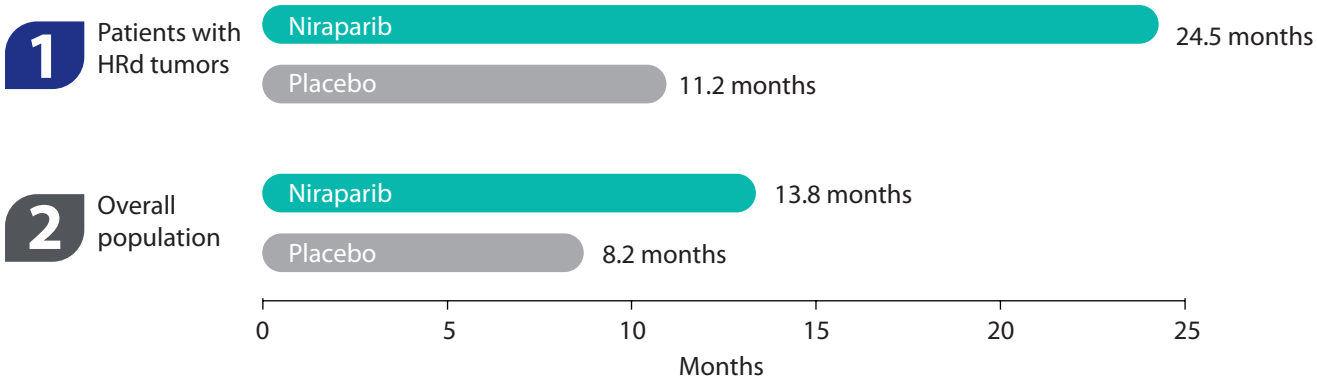
Adapted from MR Mirza, A González-Martín, WS Graybill, et al. A plain language summary of publication of the efficacy and safety of individualized niraparib dosing based on baseline body weight and platelet count in the PRIMA/ENGOT-OV26/GOG-3012 trial. Future Oncol. 2023. doi: 10.2217/fon-2023-0755

When patients with cancer are treated, genetic testing can be used to help identify patients who are likely to receive an increased benefit from certain treatments. In ovarian cancer, tumor HR status is important, because HRd tumors, including those with *BRCA* gene mutations, have been shown to respond better to PARP inhibitors.

In the PRIMA study, all patients were required to submit a tumor sample for genetic testing. However, tumor HR status was not determined in some patients, either because the results from the genetic testing were inconclusive or for some reason the tumor sample was not tested. For evaluation, patients whose tumor HR status was not determined were grouped with patients with HR-proficient tumors in the non-HRd group.

Niraparib treatment significantly delayed cancer from coming back or getting worse compared with placebo in patients with HRd tumors (which included patients with *BRCA* mutations) and in the overall population.

Median time to cancer coming back or getting worse



The median is the middle value when all values are sorted from lowest to highest. Therefore, half of the patients had a shorter time until the cancer came back or got worse and half of the patients had a longer time until the cancer came back or got worse than the numbers presented above.

Among the patients remaining on observation 4 years after starting in the PRIMA study, patients treated with niraparib were notably more likely to be free from the cancer coming back or getting worse than patients treated with placebo. As noted previously, depending on when patients began participating in the PRIMA study, they may have participated in the PRIMA study for more than or less than 3.5 years. Patients could have begun participating in the PRIMA study as early as July 2016 or as late as June 2018.

Percentage of patients who were free from ovarian cancer coming back or getting worse at 4 years

1 Patients with HRd tumors (includes patients with *BRCA* mutations)

38% Niraparib **versus** 17% Placebo

2 Overall population (patients with and without HRd tumors)

24% Niraparib **versus** 14% Placebo

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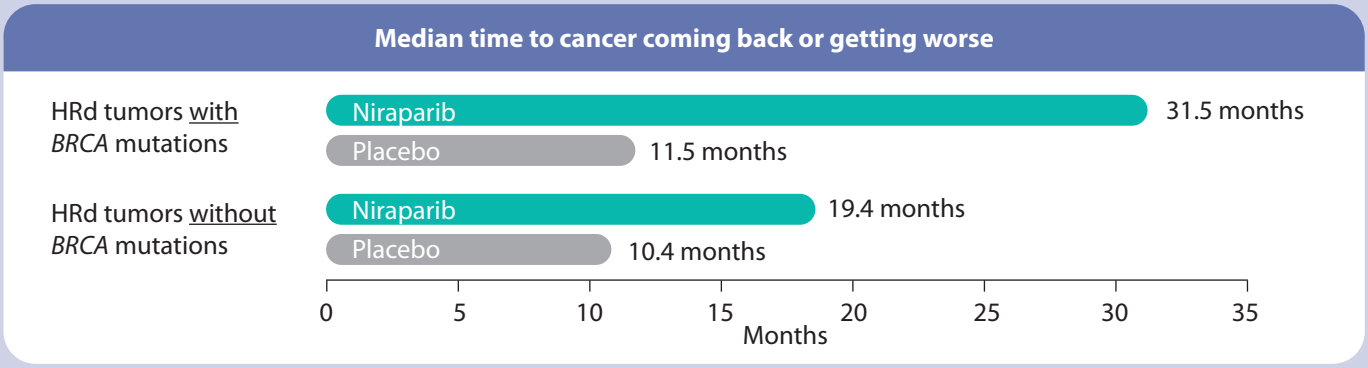
The greatest benefit of niraparib treatment was seen in patients with HRd tumors that also had *BRCA* mutations.



In addition to understanding whether niraparib could delay the cancer from coming back or getting worse, the PRIMA study also evaluated whether niraparib could extend the total time a patient lived, known as overall survival. But, at the time these results from the PRIMA study were evaluated, not enough time had passed to determine overall survival findings.

What were the safety findings?

To evaluate treatment safety, researchers track side effects that develop after patients start treatment. A side effect is any unintended, unpleasant, or harmful symptom a patient develops when taking a drug. Side effects may be directly related to the drugs received as part of the study, while others may occur at random times during study treatment. Side effects can vary in how much they affect the patient. They can be mild, moderate, severe, or even life-threatening, and can require treatment to manage. Side effect severity is graded on a scale from 1 to 5, with 5 being the most severe. Side effects that are grade 3 or higher are considered severe.

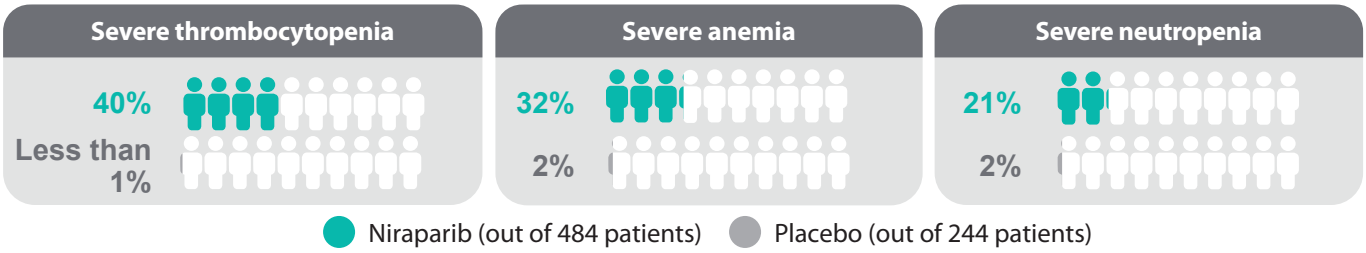
To understand if the safety of niraparib changed over time, researchers tracked side effects that occurred within the additional time being monitored as a part of the PRIMA study.

After a median of 3.5 years participating in the PRIMA study:

- **99%** of patients receiving niraparib and **94%** of patients receiving placebo experienced side effects of any severity
- **73%** of patients receiving niraparib and **23%** of patients receiving placebo experienced any severe side effects

Niraparib is known to cause blood cell–related side effects. These side effects can affect how many cells of certain types patients have in their blood. For example, niraparib treatment can reduce the number of red blood cells, which are important for carrying oxygen throughout the body, or neutrophils, a type of white blood cell important for fighting infections. The amount of platelets in the blood can also be reduced by niraparib. Platelets, also known as thrombocytes, are small fragments of cells that are important in forming blood clots to stop bleeding.

Some of the most common severe blood cell–related side effects are summarized here.



Severe thrombocytopenia: Low levels of thrombocytes, also known as platelets, which can cause problems with clotting, so cuts bleed for longer. Patients with severe thrombocytopenia may also bleed more easily.
Severe anemia: Low levels of red blood cells, which can cause tiredness.
Severe neutropenia: Low levels of neutrophils, a type of white blood cell, which can make it harder to fight off infections.

Compared with the first results from the PRIMA study, which reported results after about 1.2 years of participation in the PRIMA study:

4 additional patients receiving niraparib experienced severe thrombocytopenia

3 additional patients receiving niraparib experienced severe anemia

3 additional patients receiving niraparib experienced severe neutropenia

The most common side effects not related to blood cells in patients treated with niraparib were nausea, constipation, fatigue, headache, insomnia, abdominal (stomach) pain, vomiting, joint pain, increased blood pressure, and diarrhea. For some side effects, the oncologist may direct a patient to take a lower **dose** of the drug (dose reduction) or temporarily stop (pause) taking the drug (dose interruption). In patients receiving niraparib, 72% experienced a side effect leading to a dose reduction, and 80% experienced a side effect leading to a dose interruption.

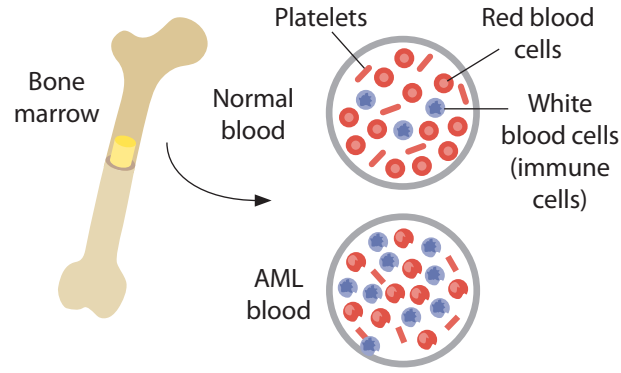
In the 2019 article that reported results after about 1.2 years of participation in the PRIMA study, 58 patients discontinued niraparib because of a side effect.

- In this analysis, patients participated in the PRIMA study for about 3.5 years.
- With additional time as part of the study, 11 new patients discontinued niraparib because of a side effect.

Dose: The prescribed amount of drug that a patient should take and how often they should take it.

After treatment for advanced ovarian cancer, a small number of patients may go on to develop types of blood cancer called myelodysplastic syndrome (MDS) or acute myeloid leukemia (AML).

MDS and AML are types of leukemia, or blood cancer. In MDS and AML, new cells that will eventually become **white blood cells** become abnormal and start to grow faster than usual. Blood cells are made in the bone marrow, which is the center, spongy part of bones. In MDS and AML, abnormal new white blood cells fill the bone marrow, reducing the body's ability to make mature blood cells. MDS and AML exist along a spectrum, or range. MDS generally occurs first and patients have fewer abnormal cells and other changes to the blood. If MDS gets worse (more and more abnormal new white blood cells are produced), it becomes AML. Patients may be diagnosed with either MDS or AML. Development of MDS/AML is a known complication of cancer treatments, including both chemotherapy and PARP inhibitors.

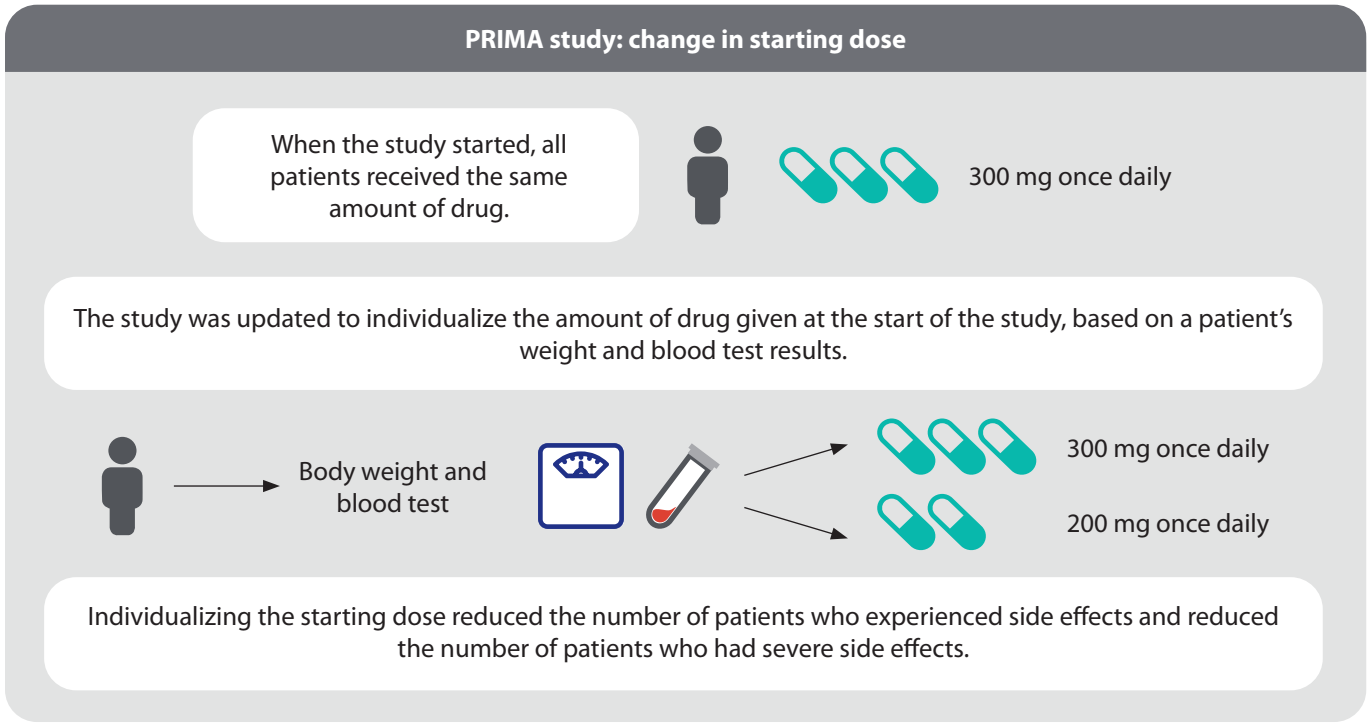


White blood cells: Different types of immune cells that help fight infection.

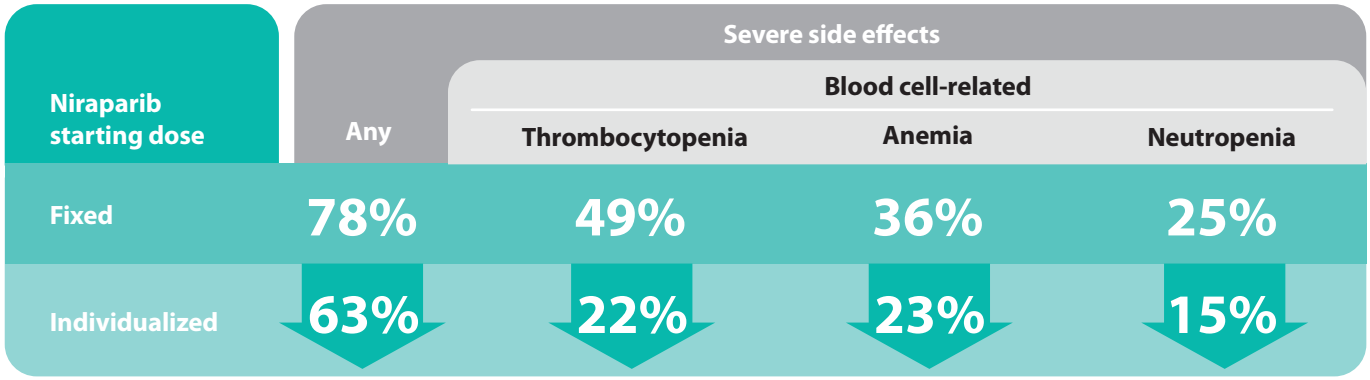
1.2%
of patients receiving niraparib or placebo developed MDS/AML

The same proportion of patients developed MDS/AML after receiving niraparib or placebo. Because patients continued to be monitored as part of the PRIMA study after they stopped receiving study treatments, patients included in this analysis could have received other, non-PRIMA study treatments after they experienced their cancer coming back or getting worse. Of the patients who developed MDS/AML, 3 of 6 patients treated with niraparib and 3 of 3 patients treated with placebo received additional chemotherapy, and all 3 patients treated with placebo later received PARP inhibitor treatment.

The amount of drug (dose) given when a patient first starts treatment is known as the starting dose. In the PRIMA study, the starting dose was changed partway through the study. The change was made to try to improve niraparib safety by reducing the number of side effects.



Individualizing the starting dose reduced the proportion of patients taking niraparib who experienced severe side effects overall and for blood cell–related side effects in particular.



The individualized starting dose also reduced the proportion of patients taking niraparib who experienced dose reductions and dose interruptions because of side effects. Treatment with the individualized starting dose of niraparib also delayed the cancer from coming back or getting worse compared with placebo. Patients treated with the individualized starting dose of niraparib had similar results compared with patients treated with the fixed starting dose of niraparib.

Overall, no new types of side effects with niraparib treatment were observed with additional time being monitored as part of the PRIMA study.

How do these results help patients and physicians?

These results show that niraparib continued to significantly delay the cancer from coming back or getting worse compared with placebo over at least 3.5 years. No new types of side effects or safety concerns were found in patients treated with niraparib who were monitored for longer periods. Niraparib remains an important maintenance therapy option for patients with newly diagnosed ovarian cancer.

Where can readers find more information?

The PRIMA study

The full name of the PRIMA study is:

- A study of niraparib (GSK3985771) maintenance treatment in participants with advanced ovarian cancer following response on front-line platinum-based chemotherapy

PRIMA study details:

- You can read more about the PRIMA study design and status by visiting this link: https://clinicaltrials.gov/ct2/show/NCT02655016
- At the time of this publication, the PRIMA study is ongoing but no longer accepting new patients
- Study number: NCT02655016
- Study sponsor: GSK

The article this PLSP is based on was published in the *European Journal of Cancer* in 2023:

- The full title of the article is 'Progression-free survival and safety at 3.5 years of follow-up: results from the randomised phase 3 PRIMA/ENGOT-OV26/GOG-3012 trial of niraparib maintenance treatment in patients with newly diagnosed ovarian cancer'
- The full citation for the article is González-Martín A, Pothuri B, Vergote I, et al. Progression-free survival and safety at 3.5 years of follow-up: results from the randomised phase 3 PRIMA/ENGOT-OV26/GOG-3012 trial of niraparib maintenance treatment in patients with newly diagnosed ovarian cancer. Eur J Cancer. 2023;189:112908. doi: 10.1016/j.ejca.2023.04.024
- You can read the free-to-access article by visiting this link: https://www.ejcancer.com/article/S0959-8049(23)00225-3/fulltext

The first results from the PRIMA study were published in 2019 in the *New England Journal of Medicine*:

- The full title of the article is 'Niraparib in patients with newly diagnosed advanced ovarian cancer'
- The full citation for the article is González-Martín A, Pothuri B, Vergote I, et al. Niraparib in patients with newly diagnosed advanced ovarian cancer. N Engl J Med. 2019; 381(25):2391–2402. doi: 10.1056/nejmoa1910962
- You can read the free-to-access article by visiting this link: https://www.nejm.org/doi/full/10.1056/NEJMoa1910962
- A PLSP of the article can be accessed by visiting this link: https://www.trialsummaries.com/Study/StudyDetails?id=14456&tenant=MT_GSK_9011

The detailed results describing the individualized starting dose findings were published in 2023 in the journal *Cancer*:

- The full title of the article is 'Prospective evaluation of the tolerability and efficacy of niraparib dosing based on baseline body weight and platelet count: results from the PRIMA/ENGOT-OV26/GOG-3012 trial'
- You can read the free-to-access article by visiting this link: https://acsjournals.onlinelibrary.wiley.com/doi/epdf/10.1002/cncr.34706

Partnership with ENGOT and GOG

The PRIMA study was conducted in partnership with ENGOT and GOG and is also known as the ENGOT-OV26 study and the GOG-3012 study. ENGOT stands for the European Network for Gynaecological Oncological Trial groups, and GOG stands for the Gynecologic Oncology Group. Both groups are dedicated to promoting research to improve care for patients with gynecologic cancers.

Educational resources

Read more about ovarian cancer at:

- The American Cancer Society website: https://www.cancer.org/cancer/ovarian-cancer.html
- The European Society for Medical Oncology website: https://www.esmo.org/for-patients/patient-guides/ovarian-cancer
- The ENGAGe Network from the European Society of Gynaecological Oncology: https://engage.esgo.org/brochures/cancer-fact-sheets/ovarian-cancer/

Affiliation information

[1]Medical Oncology Department, Cancer Center Clínica Universidad de Navarra, Madrid, Program in Solid Tumours, CIMA, Pamplona, and Grupo Español de Investigación en Cáncer de Ovario (GEICO), Madrid, Spain; [2]Gynecologic Oncology Group (GOG Foundation), NYU Langone Health, Department of Obstetrics & Gynecology, Perlmutter Cancer Center, New York, NY, USA; [3]Belgium and Luxembourg Gynaecological Oncology Group (BGOG), Department of Gynaecology and Obstetrics, Division of Gynaecological Oncology, University Hospitals Leuven, Leuven Cancer Institute, Leuven, Belgium, European Union; [4]GOG, Gynecologic Oncology, Medical University of South Carolina, Charleston, SC, USA; [5]Multicentre Italian Trials in Ovarian Cancer and Gynecologic Malignancies (MITO), Fondazione Policlinico Gemelli IRCCS and Catholic University of Sacred Heart, Rome, Italy, when the study was conducted; present affiliation Humanitas San Pio X, Milan, Humanitas University, Rozzano, Italy; [6]GOG, Legacy Medical Group Gynecologic Oncology, Portland, OR, USA; [7]Groupe d'Investigateurs Nationaux pour l'Etude des Cancers Ovariens (GINECO), HCL Cancer Institute, Department of Medical Oncology, Lyon University, Lyon, France; [8]Division of Gynecologic Oncology, Ohio State University, Columbus, OH, USA; [9]AGO Study Group and the Department for Gynaecology and Gynaecologic Oncology, Kliniken Essen-Mitte, Essen, and Charité - Universitätsmedizin Berlin, Humboldt- Universität zu Berlin, Berlin Institute of Health, Department of Gynaecology, Berlin, Germany; [10]GEICO, Department of Medical Oncology, Hospital Universitario La Paz–IdiPAZ, Madrid, Spain; [11]Division of Gynecologic Oncology, Wilmot Cancer Institute, Department of Obstetrics and Gynecology, University of Rochester, Rochester, NY, USA; [12]BGOG, Department of Medical Oncology and Hematology, AZ Maria Middelares, Gent, and Department of Molecular Imaging, Pathology, Radiotherapy & Oncology, Center for Oncological Research, Antwerp University, Antwerp, Belgium; [13]GOG, Gynecologic Medical Oncology, Memorial Sloan Kettering Cancer Center, and Department of Medicine, Weill Cornell Medical College, New York, NY, USA; [14]GSK, Middlesex, UK; [15]Department of Oncology, Rigshospitalet–Copenhagen University Hospital and Nordic Society of Gynaecological Oncology, Copenhagen, Denmark; [16]HonorHealth Research Institute, University of Arizona College of Medicine, Phoenix Creighton University, Phoenix, AZ, USA, when the study was conducted; present affiliation GOG Foundation; Florida Cancer Specialists and Research Institute, West Palm Beach, FL, USA.

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