Should I Take Niraparib For My Ovarian Cancer?

A decision aid to discuss options with your doctor



This decision aid is for you if:

- You have advanced ovarian cancer of high grade serous or endometrioid type.
- You have finished your first treatments (surgery and chemotherapy).
- Your tumour has been tested and we have found no genetic cause for your cancer.



What are high grade serous and endometrioid ovarian cancers?

Ovarian cancers are grouped on how they appear under the microscope. High grade serous and endometrioid ovarian cancers are the two most common types. People that have one of these types of ovarian cancer and who respond to their initial chemotherapy are eligible to take a new class of drugs called PARP inhibitors (PARPi).



Why did we test your tumour?

We are able to test your tumour (cancer) for genetic changes to predict how your cancer will respond to certain drugs. We tested your cancer for an abnormality called Homologous Recombination Deficiency (HRD). This test measures the ability of your cancer to repair its DNA as the cells divide and grow. About half of all ovarian cancers have a defect in their ability to repair DNA, and half do not. The results of tumour testing are useful because we can predict how much benefit you could get from taking a PARPi. In your case, this means that the amount of benefit from taking a PARPi is about a 3-month delay to the next chemotherapy treatment. This does not mean that you will live longer



What is a PARP inhibitor?

Niraparib is the name of the only PARPi currently available to treat your cancer in Canada. Niraparib works by preventing cancer cells from repairing their DNA as they grow and divide. Fixing DNA in cells is a complex two-step process:

- A key first step in DNA repair needs normal genes and enzymes (protein) that repair DNA by a process called Homologous Recombination.
- DNA can also be repaired using an enzyme (protein) called PARP, and cells
 depend on this repair process if they already have impaired or missing
 Homologous Recombination genes and enzymes (proteins).

In other words, Niraparib works best if the main genes that repair DNA are damaged or missing (Homologous Recombination Deficient - HRD). In your case, the testing shows that your DNA repair genes are intact (Homologous Recombination Proficient - HRP) so it is not clear that taking the Niraparib will be helpful to you.

What are your treatment options?







Take Niraparib

Niraparib is a pill taken by mouth once a day. It is started 12 weeks after chemotherapy is done. When taking Niraparib, you will be checked often for side effects and have bloodwork done weekly for 4 weeks. Then bloodwork is done less often. There is no cost for taking this treatment if you live in Canada.

Do Not Take Niraparib

Take a break from treatment or ask your doctor about other options such as clinical trials.

What other health factors may affect your choice?

Check \checkmark any that apply to you and discuss with your doctor.



Working through the 4 steps of this decision aid may help you think about your options and make the best choice for your health and well-being.

Step 1: What Are The Benefits And Harms/Side Effects Of Each Option?

What does the research show?

Each side effect below shows a 'best estimate' of what happens to 100 People with ovarian cancer who take Niraparib or who do not take Niraparib. In general, most of these side effects will occur over the first 4 to 6 weeks of treatment and slowly go away over 3 months of treatment. If serious side effects occur with Niraparib, the doctor can try to manage these with a lower dose or a short-term break from Niraparib. There is no way of knowing in advance if you will have these side effects. This information about the chance of having a side effect is taken from a study of Niraparib called the PRIMA trial. The side effects are listed from most common to least common and happened more than 10% of the time. Some of the rarer side effects can be very severe and we have made a list of these at the end of the decision aid. Death from taking Niraparib is very unlikely. If you want more information on these rare side effects, ask your doctor.

Benefits

In the future, you will be offered more chemotherapy. Taking Niraparib may delay this offer of chemotherapy by about 3 months. There is no data that Niraparib can prolong your life.

Harms/Side Effects

Like all drugs, Niraparib has a number of side effects. Some of these are serious. Understanding the side effects of this drug will help you decide whether Niraparib is right for you.

Icon information

- Teal means mild to moderate
- Orange means severe to life-threatening³



Low Platelet Numbers

- If 100 people take Niraparib, 66 will have low platelet numbers (Thrombocytopenia).
- If 100 people do not take Niraparib, 5 will have low platelet numbers (Thrombocytopenia).
- Low platelet counts range from just a low number on your bloodwork to a risk of bleeding that might require a platelet transfer.
- The average time until symptoms of low-platelet numbers start is 22-23 days. Symptoms last from several days to several weeks. Symptoms improve after the third month of treatment.

Niraparib

66 have low platelet numbers, 34 do not

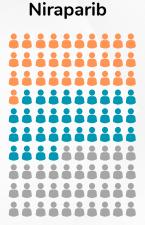
No Niraparib

- Teal means mild to moderate
- 3
- Orange means severe to life-threatening³



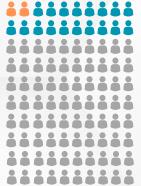
Low Red Blood Cell Numbers

- If 100 people take Niraparib, 64 will have low red blood cell numbers (Anemia).
- If 100 people do not take Niraparib, 18 will have low red blood cell numbers (Anemia).
- Symptoms of Anemia range from mild tiredness to severe exhaustion and weakness that affect daily activities. Blood and/or iron transfusion may be needed.



64 have low red blood cell numbers, 36 do not

No Niraparib

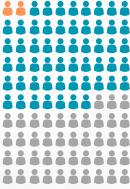


18 have low red blood cell numbers, 82 do not

Nausea

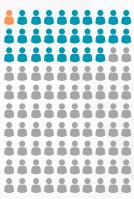
- If 100 people take Niraparib, 57 will have nausea.
- If 100 people do not take Niraparib, 28 will have nausea. Nausea is the feeling of sickness and need to vomit. Symptoms of nausea may include not feeling hungry and needing pills to decrease nausea to treatment in hospital with IV fluids and food supplement may be needed. Nausea often improves after the third month of treatment.

Niraparib



57 have nausea, 33 do not

No Niraparib



28 have nausea, 72 do not

Fatigue

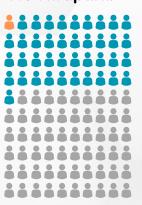
- If 100 people take Niraparib, 51 will have fatigue.
- If 100 people do not take Niraparib, 41 will have fatigue. Symptoms of fatigue (weakness, exhaustion, and decreased mental sharpness range from mild to severe, being less able to function and causing physical and mental distress.
- Fatigue may be helped by staying active but there is no treatment.
- Fatigue may lead to trouble driving or using machinery. Fatigue may improve after the third month of treatment.

Niraparib



51 have fatigue, 49 do not

No Niraparib



41 have fatigue, 59 do not

- Teal means mild to moderate
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Low White Blood Cell Numbers

- If 100 people take Niraparib, 42 will have low white blood cell numbers (Neutropenia).
- If 100 people do not take Niraparib, 8 will have low white blood cell numbers (Neutropenia).
- Symptoms of Neutropenia range from just a low number on your bloodwork to infection (needing pills to treat the infection) to very serious wholebody infections needing a stay in the hospital and IV fluids and antibiotics.



42 have low white blood cell numbers, 58 do not

No Niraparib

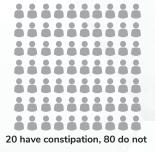
8 have low white blood cell numbers, 92 do not

No Niraparib

Constipation

- If 100 people take Niraparib, 40 have constipation.
- If 100 people do not take Niraparib, 20 have constipation.
- Constipation may require some use of stool softner to regular use of stool softener.

Niraparib



No Niraparib

Headaches

- If 100 people take Niraparib, 26 will have headaches.
- If 100 people do not take Niraparib, 15 will have headaches. Headaches are generally considered to be mild and managed with over the counter pain killers.

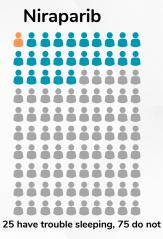


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- Orange means severe to life-threatening



Trouble sleeping

- If 100 people take Niraparib, 25 will have trouble sleeping or staying asleep (insomnia).
- If 100 people do not take Niraparib, 14 will have trouble sleeping or staying asleep (insomnia).
- Symptoms of insomnia range from mild trouble sleeping to being unable to sleep and needing prescribed pills.

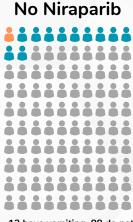




Vomiting

- If 100 people take Niraparib, 22 will have vomiting.
- If 100 people do not take Niraparib, 12 will have vomiting. Vomiting ranges from vomiting one to six times per day to vomiting more than six times per day requiring hospitalization and IV fluids.
- Symptoms improve after the third month of treatment.

Niraparib 22 have vomiting, 78 do not

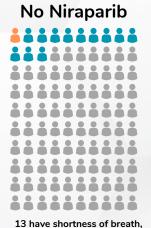


12 have vomiting, 88 do not

Shortness of breath

- If 100 people take Niraparib, 22 will have shortness of breath (dyspnea).
- If 100 people do not take Niraparib, 12 will have shortness of breath (dyspnea).
- Shortness of breath ranges from shortness of breath that limits activity to shortness of breath that occurs at rest, or needs treatment such as a puffer.





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Decreased Appetite

- If 100 people take Niraparib, 19 will have decreased appetite.
- If 100 people do not take Niraparib, 8 will have decreased appetite.
- Symptoms of decreased appetite range from eating less or altered eating habits which may require pills to increase hunger or weight loss needing food supplements.



19 have decreased appetite, 81 do not

No Niraparib

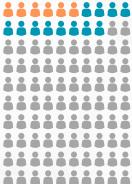


92 do not

High Blood Pressure

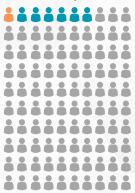
- If 100 people take Niraparib, 18 will have high blood pressure. If 100 people do not take Niraparib, 7 will have high blood pressure.
- You may not have any symptoms and this is just a finding at your doctor's visit. Sometimes, there can be symptoms such as shortness of breath, headache or fatigue. Prescribed pills may be needed.
- Blood pressure and heart rate need to be checked weekly for the first month, then monthly.

Niraparib



18 have high blood pressure, 82 do not

No Niraparib

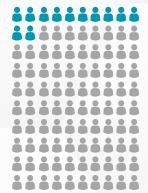


7 have high blood pressure, 93 do not

Kidney Function

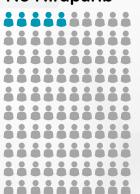
- Kidney Function
- If 100 people take Niraparib, 12 will have an effect on kidney function (as shown on your bloodwork).
- If 100 people do not take Niraparib, 5 will have an effect on kidney function (as shown on your bloodwork).
- You may not have any symptoms other than a change in your blood pressure result.
- Drinking more fluids can reduce the negative effects of Niraparib on the kidneys.

Niraparib



12 have an effect on kidney function, 88 do not

No Niraparib



5 have an effect on kidney function, 95 do not

Step 2: What Matters Most To You?

Common reasons to choose each option are listed below.

Check \checkmark how much each reason matters to you on a scale from 1 to 5. '1' means it is not important to you. '5' means it is very important to you.

Not In	Important Important				rtant
Reasons to take Niraparib	1	2	3	4	5
How important is it to try every treatment option available to you?					
How important is it to delay the start of your next chemotherapy?					
Other:					

No.	t Import	Important -			Important		
Reasons not to take Niraparib	1	2	3	4	5		
How important is it to you to avoid the chance of side effects that impact your quality of life?							
How important is it to you to avoid taking pills daily?							
Other:							

Now, think about which option has the reasons that are most important to you...

Which	option do you prefer?
Check	one 🗸
	Take Niraparib
	Do not take Niraparib
	Discuss other options with your doctor

Step 3: What Else Do You Need to Prepare for Decision Making?

Find out how well this decision ai	d helped	you lear	rn the ke	ey facts
Check ✓ the best answer	Take Niraparib	Do not take Niraparib	Neither	l don't know
 Which option has the highest chance of giving me more time before my next treatment? Which option has the chance of fewer side 				
effects?				
 Which option has the chance of more side effects? 				
Which option will help you live longer?				
This information is not meant to replac	e the advi	ce of a hea	lthcare pr	ovider.
Step 3 answers: 1. Take Niraparib, 2. Do not take Ni	raparib, 3. Ta	ıke Niraparib, 4	4. Neither	
Find out how comfortable you feel				ion. ⁴
 Do you know the benefits and harms/side effect of each option? 		es	No	
 Are you clear about which benefits and harms/side effects matter most to you? 				
 Do you have enough support and advice to mak a choice? 	e [
 Do you feel sure about the best choice for you? 				
If you answered 'No' to any of these questions, dis	cuss with you	ur doctor.		
Step 4: What Are T	he N	lext S	teps	
Check ✓ what you would like to do next.				
I have decided to take Niraparib.	have decided	I not to take N	iraparib.	
I need to discuss the options with my doctor and	d my family.			
I need to read more about my other options				
Other (Please specify)				

You are invited to discuss all the contents of this survey including your responses with your physician.

Serious and rare potential side effects (less than 10/100 people);

- Leukemia
- Bone marrow failure
- Severe swelling of the eyes, lungs, liver, kidneys, legs, and/or brain
- · Skin easily burns when exposed to sunlight
- Sudden, severe increase in heart rate and/or blood pressure
- Serious allergic reaction
- Low potassium
- Depression, confusion, seeing things that are not there

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This decision aid meets the criteria outlined by the International Patient Decision Aids Standards (IPDAS).

• For more general information about Niraparib, read the hyperlinked article or contact your doctor. https://www.mayoclinic.org/drugs-supplements/niraparib-oral-route/side-effects/drg-20406195?p=1.

Benefits and harms data taken from:

The best data we have comesfrom the PRIMA trial. There is no other trialthat has been done so far that can help patients with this treatment choice. If and when another helpful trial is done, we will update this resource.

- 1. Moore, K., Colombo, N., Scambia, G., Kim, B.-G., Oaknin, A., Friedlander, M., Lisyanskaya, A., Floquet, A., Leary, A., Sonke, G. S., Gourley, C., & Banjeree, S. (2018, December 27). Maintenance Olaparib in patients with newly diagnosed advanced ovarian ... The New England Journal of Medicine. Retrieved April 5, 2023, from https://www.nejm.org/doi/full/10.1056/NEJMoa1810858
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- 4. The SURE Test © O'Connor & Legare, 2008.