

Know about the BioDiva research study

Read this pamphlet to:

- Know why this study is being done
- Know what taking part in this study involves

BioDiva

The study of
biomarkers in
ovarian cancer



What you need to know about the BioDiva study

What is a clinical trial?

A clinical trial is a research study that involves humans.

Who can take part in this study?

You can take part in this study if all of the below apply to you:

- You have High Grade Serous Ovarian Cancer (HGSOC).
- You are about to start chemotherapy or drug treatment to reduce the size of your tumour.
- You are about to have a biopsy or surgery. The surgery is to remove as much of your cancer as possible before you start chemotherapy.

Why is this study important?

HGSOC is the most common type of ovarian cancer.

When HGSOC is first diagnosed (found), the cancer responds well to surgery and chemotherapy. However, in many women, HGSOC comes back.

When HGSOC returns it can be hard to control and treat. HGSOC is hard to treat because the biology (or make up) of the cancer has changed.

When these changes can be measured, it is called a biomarker. Biomarkers are found in blood, fluid or tissues. Cancer itself, or the body's response to cancer, may produce biomarkers.

This study seeks to find out how HGSOC changes by getting information about biomarkers in your cancer.

The study team hopes to discover:

- How HGSOC changes from the first time it is diagnosed to when it returns.
- How to detect these changes in your blood.



What does the study team hope to learn?

From this information, the study team hopes to:

- 1 Develop new targeted treatments. A targeted treatment is a drug that may be able to block cancer cell changes.
- 2 Develop a series of tests that can quickly tell doctors if a patient's treatment is not working. These tests will allow doctors to make changes to treatment faster.
- 3 Develop new tools to detect cancer early when it comes back. These new tools will be used to create early screening programs. At this time, there are no screening tools to catch HGSOC early before it has spread to other organs.

To develop these new drugs and tools, the study team needs to track HGSOC as closely as possible.

What you need to know about taking part in the BioDiva study



How long will the study last?

Your time in the study may vary. You may be in the study for up to 2 years.

While in the study, the team will collect information about how your cancer responds to your cancer treatment. The team will get this information from:



your medical records

or



calling you every 3 - 6 months for a brief follow-up.

What do I have to do?

If you decide to take part in the study, you will need to allow the study team to collect:



Tumour tissue samples. Samples will come from:

- tumour tissue that has already been removed during surgery.
- a biopsy (a small sample of tissue taken from your body without surgery).



Blood samples. You will need to have blood samples taken:

- at the start of the study.
- when you have your surgery (if you are having surgery).
- if you get:
 - a CT scan.
 - an MRI scan.
 - an ultrasound or x-ray during your cancer treatment and follow-up.
- if your cancer gets worse or comes back.



Other samples. These samples will come from any fluid that is drained from your:

- lungs.
- stomach area.
- or a cyst on your tumour (a cyst is a sac of fluid).

You will not receive any medicine as part of this study.

What will the study use the samples for?

The samples will only be used for research. The study will use the samples to gather information on how your cancer behaves. This information may help guide treatment options for you.

The study may also test samples to find out if cancer runs in your family. Testing for cancer in families is called hereditary genetic testing. If you have gene changes (mutations), your family members may have the same gene changes.

Gene changes may mean your family members have a higher risk for cancer. The study will only check samples for gene changes that cause cancer.

If gene changes are found, the study team will also arrange for you and your family to meet with genetic experts. You can choose to get these results or not. You can also choose to have a family member get this information, in case you are unable to get it.

Do I need to come to the hospital or cancer centre just for this study?

You should not need to make extra trips to the hospital for this study.

The study team will try to collect samples when you come to the hospital for routine visits. If you have a change in your cancer and need a biopsy, the team will arrange this.

Who do I see during the study? Do I still see my regular cancer doctor?

You will see your regular health care team during this study.

Will I have to pay for anything?

You will not have to pay for anything that is part of the study.

Will I get paid for taking part in the study?

You will not get paid for taking part in this study. You will not get paid if new tests, drugs or other products result from this study.

You do not have to be in the study. If you agree to take part, you can stop at any time.

What are the risks of taking part in this study?

If you choose to take part in this study, you may get some of the side effects listed below. You should discuss these with your doctor.



When getting blood taken, you may have:

- pain
- bruising
- bleeding
- swelling and redness of the vein
- infection where the needle was put in



When having a tumour biopsy, you may have:

- pain
- bruising
- infection
- bleeding at the area where the biopsy was taken



The risks of genetic information:

- There is a low risk that someone could trace your genetic information in a central database back to you. The study team believes the risk of someone knowing who you are from this information is very small.

All the information you share will be kept private and anonymous (without your name or contact details on it).

Talk to a member of your cancer care team, if you would like to take part in this study.

If you would like more information visit www.GyneCancerStudies.ca

You can find information about this study on www.clinicaltrials.gov. This website will not include information that can identify you. At most, the website will include a short report of the study results. You can search this website at any time.

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