Patient Information Sheet (PIS)

NUGENA

Nurse led Genetic counselling in improving Awareness and implementation of screening services for hereditary women's cancer

Patient Screening/Randomization Number: _____

Patient's Initials: _____

Name of the study site: _____

Please go through each of the sections carefully before making a decision. Participation is completely voluntary.

Information for patients

You have been invited to participate in this study because your doctors tell us that you have been diagnosed with or treated for ovarian cancer and you have been offered genetic testing. This is to look for the presence of gene alterations (or mutations) that cause ovarian cancer.

To help you decide, it is important for you to understand the purpose of this study and what it will involve. Please take time to read this leaflet carefully. Do discuss it with others (your family, friends or healthcare professional) if you wish. Please ask if there is anything you do not understand. Please do let us know if you would like more information. Our contact details are at the end of the information sheet.

Why is the study being done?

This research study aims to understand the impact of nurse led genetic counseling in a tertiary cancer center for awareness and education on cancers. The genetic nurse in the institute will guide you regarding your cancer and its association with genes, and how it can be tested, what are the implications of the test and how such hereditary cancers can be prevented in the patient and family, if diagnosed early. To do this, we will assess for any genetic mutations in you and your family, and look at the number of gene alterations found in women with ovarian cancer. We will also look at your expected cost for the testing, in a sub study called Willingness to Pay study.

In addition, we are interested in collecting ovarian cancer tissue and blood samples. We will also collect information about your health and well--being. This will help identify genetic and non--genetic factors that affect ovarian cancer risk, treatment and outcomes

What does the study involve?
You may have received and read the information leaflet titled "Information sheet for genetic testing in cancer of the ovary, fallopian tube and primary peritoneal cancer". We offer a genetic test to women with certain types of ovarian cancer. This is to detect gene alterations that may be a cause of ovarian cancer. The test usually looks for alterations in the following genes: **BRCA1**, **BRCA2**, **RAD51C**, **RAD51D** and **BRIP1**. At present, testing for changes in the genes **BRCA1 and BRCA2 is** standard practice,which we will conduct in our study. Testing for the additional genes (RAD51C, RAD51D, BRIP1) is not done in our study since they are moderate to low risk genes and do not posess severe threat as BRCA 1 and 2.We are keen to find out how women feel about genetic testing and counseling from a nurse genetic counselor. We are also interested to find the willingness to pay for the study in various hypothetical scenarios.

In addition, we hope to collect important information about ovarian cancer. Ovarian cancer is a complex disease with many areas that are still not well understood. The aim is to identify genetic and non--genetic markers related to the risk and outcomes of ovarian cancer. This along with information available on your health will help us develop a better understanding of ovarian cancer. It will help improve methods of prediction, prevention, diagnosis and treatment of ovarian cancer.

The aim of the study is:

- To identify whether implementation of a nurse led genetic clinic in locoregional centres (hub and spoke model) supported by patient public involvement initiatives is a cost-effective strategy for hereditary women's cancer prevention
- The impact of genetic testing for high risk *genes (*BRCA1 and 2*)*, on the health economic and quality of life of ovarian cancer patients.
- The number of gene alterations detected in women with ovarian cancer.
- The uptake of screening or preventative options and the cost effectiveness of this approach
- We are also interested in collecting ovarian cancer tissue, blood, genetic and non--genetic samples and information for research. This will look into genetic and non--genetic factors that affect ovarian cancer risk, treatment and outcomes

What are the side effects?
There are no side effects associated with genetic testing. Since it is blood test, signs associated with needle prick will occur.

Why is this research being done?
Although genetic testing for high grade serous cancer patients are available all over the world, in India it is relatively few and quite expensive. Our cancer services at Chittaranjan National Cancer Institute, in coordination with KolGoTrg, offers genetic testing at a reasonable price to patients diagnosed with certain types of cancer affecting the ovary, fallopian tube or

peritoneum. It is hoped that by doing this, patients across West Bengal will have even better treatments and that in some families, cancers will be prevented.

What happens after I consent?
After your consent you would be counselled about genetic testing by the nurse genetic counsellor. The genetic counsellor will guide you regarding hereditary cancers, how it can be diagnosed through blood tests, implications in your treatment or follow ups if the report comes positive and how your family members will be tested and followed up accordingly.

What happens if I decide to take part?
If you decide to take part in this study, your doctor will register your details with the KolGOTrg CTC. We will ask you to sign a form to give your consent to take part in the study. We would also collect a biobank consent form stating that we would collect some of your tissue or body fluids such as ascitic fluid or blood at some time points to be stored in biobank for future studies. You will then be counselled about hereditary cancers and genetic testing and how it will affect your future treatments and follow ups. You will also be described about cascade testing, i.e. testing of your family members.

What medical tests are involved?
The medical tests that are required is a blood test to diagnose germline mutations in BRCA 1 and 2.

What if I change my mind?
If, after deciding to take part, you change your mind, you can withdraw from the trial at any time. This will not affect your relationship with the doctors or nurses, or your subsequent care, in any way. Some information on your progress will continue to be collected even if you leave the trial so that the long-term effects of your treatment can be assessed.

What if something goes wrong?
KolGOTrg is the sponsor of the trial and as such would give sympathetic consideration to claims for compensation for non-negligent harm that you may suffer by participating in this trial.
The hospital you are treated in continues to have a duty of care to you, whether or not you agree to participate in this trial.

What happens when the study stops?
Once you are on the trial, the doctor will continue to collect information about how you are doing. When the trial is completed, the care from your doctor will continue as planned. Your doctor will be able to advise you on treatment at all times during and after the trial.

Additional research
If you decide to take part in the study, we will ask you to fill in a brief questionnaire when you visit your doctor. The questionnaire is designed to assess how much money you are willing to

spend if genetic testing is made accessible to all at a cheaper rate by the Government. This will help future patients by giving us more information regarding the Willingness to Pay study.

Will my details be kept confidential?

If you give permission to participate in the study, you also give permission to use your medical data, as stated in your medical status, for research purposes. You hereby also give permission to combine this data with data from you from other sources in the future (sources such as cancer registries, other medical data from, for example, the doctor, etc.). All data collected from you (personal, clinical, economic and data from research on human material) will be treated in accordance with privacy legislations of India. This will mean that all your research data is registered under code and that only the treating physician and local researchers have access to the code key that can be used to identify you. Your data will not be accessible to third parties (except for the aforementioned authorities) and will only be published in non-traceable form. If you object to all this or want to know more about this, discuss this with the doctor or the KolGo Trg clinical trial coordinator.

Further information

If you have any further questions about your disease or about clinical trials, please discuss them with your doctor. Before you make a decision you may wish to have time to think about it, and discuss it with your family and friends and your family doctor. Please take as much time as you need to make a decision. If you decide to take part in this trial, you will be given a copy of this leaflet and a copy of your signed consent form to keep.

We hope that this information will help you understand the procedure. If you have any questions about this treatment, please contact:

Clinical Nurse Specialist	+918918633700

Informed Consent Form

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Please initial boxes to agree

1. I have read the patient information sheet and information leaflet on the above clinical trial and have been given a copy to keep. I have had the opportunity to ask questions about the project and understand why the research is being done and any foreseeable risks involved. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected. ☐

3. I understand that sections of any of my medical notes may be looked at by responsible individuals from KolGOTrg Research Team I give permission for these individuals to have access to my records, but understand that strict confidentiality will be maintained. ☐

4. I understand that information about me will be held by the KolGOTrg Research Team and that the unit is registered under the Data Protection Act to hold such information. ☐

5. I agree that my data can be stored and used for this clinical trial. ☐

6. I agree to take part in the above trial. ☐

…….	……	…….
Name of patient (BLOCK CAPITALS)	Date (DD/MM /YYYY)	Signature
…….	……	…….
Name of Witness (BLOCK CAPITALS)	Date (DD/MM /YYYY)	Signature
…….	……	…….
Name of Person taking Consent (BLOCK CAPITALS)	Date (DD/MM /YYYY)	Signature