

PATIENT INFORMATION SHEET

INFORMATION FOR PARTICIPANTS OF THE STUDY

1. Title of the project

A Phase III Randomized trial Of Systematic lymphadenectomy in patients with apparent Early stage high grade epithelial ovarian cancer (ROSE trial)

Official details on internet search: <https://rosetrial.org/>

2. Investigators of the study

Principal Investigator: Dr Jagannath Mishra, MS, MCh

Co-PI from TMC-K: Dr Jaydip Bhaumik, DGO, MS, DNB, FRCOG, MPH

Co Investigators from TMCK: Dr Anik Ghosh, Dr Basumita Chakraborti, Dr Subhashree Rout, Dr Aditi Chandra, Dr Priya Ghosh, Dr Jeevitesh Khoda , Dr Divya Midha, Dr Shivani Sarkar, Dr Anurag Saha, Dr Sayak Dey, Dr Prashant Pandey, Mr Subir Sinha

Invitation

You are being invited to take part in a research study because you have an ovarian tumour which is suspected to be cancerous and will be undergoing surgery as a part of the treatment.

You can choose to take part or not to take part in this study, and you can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits. This document presents important information to help you make your choice.

Please take time to read it carefully. Talk with your doctor, family, or friends about the risks and benefits of taking part in this study. It's important that you have as much information as you need, and that all your questions are answered.

3. Why is this study being done?

During surgery, a sample of the ovarian tumour will be examined immediately (frozen section examination) to determine whether it is a high-grade epithelial ovarian cancer (a cancer that has high risk of spreading elsewhere in the body). If the diagnosis is confirmed and the disease appears confined to the ovaries without any suspicion of a spread to any other organ including the glands (lymph nodes) in the abdomen that drain the fluid and cancer cells from the tumour, you may be eligible to participate in this study. As part of standard surgery, surgeons usually remove the uterus, ovaries, the tubes connecting the uterus with the ovaries (fallopian tubes), and the curtain of fat

covering the bowels in the abdomen (omentum) along with lymph nodes from the pelvis and around the major blood vessels (called systematic pelvic and para-aortic lymphadenectomy) to determine whether cancer has spread to these lymph nodes.

Although this procedure helps determine the stage of the cancer, it is not known whether removing normal-looking lymph nodes actually improves the chance of remaining disease free when other steps of the surgery are unchanged in women whose cancer appears to be confined to the ovaries and who have no enlarged lymph nodes on scans or during surgery.

Although it helps to formally stage the disease and assess the likelihood of recurrence of the disease in the future, removal of lymph nodes increases the duration of surgery and may increase the risk of complications such as:

- Injury to nearby blood vessels, nerves, or ureters
- Formation of lymphocysts (collections of lymphatic fluid)
- Swelling of the legs (lymphedema)
- Longer hospital stay, delaying recovery

The purpose of this study is to determine whether not performing systematic lymph node removal is equally effective to keep the disease away and better for outcome in post operative recovery, compared to performing systematic lymph node removal in women with apparent early-stage high-grade epithelial ovarian cancer.

The knowledge gained from this study will help improve future treatment for women with ovarian cancer by avoiding possible unnecessary surgery if it is shown to be safe and effective.

4. Will my standard treatment be affected if I choose to participate in this study or not?

No.

All participants in this study will receive the standard treatment recommended for ovarian cancer. The only difference between the two study groups is whether pelvic and para-aortic lymph nodes are removed during surgery, if the frozen section biopsy confirms high grade epithelial ovarian cancer.

All other aspects of your treatment, including:

- surgery,
- pathological examination,
- chemotherapy (if required),
- follow-up,

will be provided according to standard medical practice.

Your treating team will continue to make all decisions along with you regarding your cancer treatment.

5. Do I need to undergo any special tests before starting the study, or during and after it begins?

No additional blood tests, scans, or procedures are required solely because you participate in this study. All investigations performed before surgery, during treatment, and during follow-up are part of routine care for ovarian cancer. The study mainly records information about your surgery, recovery, complications, pathology findings, and follow-up.

6. What happens if I participate in this study?

If you agree to participate, you will first sign this informed consent form before surgery.

During your surgery, a small portion of the ovarian tumour will be examined immediately by the pathologist (called **frozen section examination**) to confirm whether it is a high-grade epithelial ovarian cancer.

If the frozen section suggests that: you have high-grade epithelial ovarian cancer, your disease appears confined to the ovaries, and there are no suspicious lymph nodes, you will be assigned to one of two treatment groups by a computer assisted method called randomisation. This is performed by a secure computer-generated system and is similar to tossing a coin. Neither you nor your surgeon can choose the treatment group.

Group A

Standard staging surgery **with systematic pelvic and para-aortic lymphadenectomy.**

Group B

Standard staging surgery **without systematic pelvic and para-aortic lymphadenectomy.**

If, during surgery, the surgeon notices any lymph node that appears enlarged or suspicious, it will be removed regardless of the group assigned because this is considered appropriate medical care.

The purpose of this study is to determine whether omission of systematic lymphadenectomy provides outcomes that are comparable to routine lymphadenectomy while reducing surgical morbidity.

After surgery, your treatment and follow-up will continue according to standard institutional practice.

7. What are the benefits of participating in this study?

You may or may not receive any direct medical benefit from participating in this study.

If you are assigned to the group in which systematic lymph node removal is omitted, the length of your surgery will be shorter and you may have a lower risk of complications related to lymph node removal, such as cystic collection of fluid (lymphocele) formation, lower-limb swelling (lymphedema), injury to nearby blood vessels or nerves, and prolonged recovery. However, these potential benefits cannot be guaranteed.

If you are assigned to the group undergoing systematic lymphadenectomy, you will receive the current standard surgical staging procedure practiced in all tertiary care institutions.

The information obtained from this study may help improve the treatment of women in the future with apparent early-stage epithelial ovarian cancer by determining whether routine systematic lymphadenectomy is truly necessary.

8. What are the risks of participating in this study?

All participants in this study will undergo major surgery for ovarian cancer, which carries the usual risks associated with anaesthesia and abdominal surgery. The study does not expose you to any experimental drugs or devices. The main difference between the two treatment groups is whether systematic pelvic and para-aortic lymph nodes are removed.

If lymphadenectomy is performed, possible risks include increased operative time, increased blood loss, injury to nearby blood vessels, nerves or ureters, lymphocyst formation, lower limb swelling (lymphedema), infection and prolonged recovery, which is a standard risk in our current practice. If lymphadenectomy is omitted, there is a possibility that microscopic cancer deposits within normal-looking lymph nodes will remain undetected. At present, it is not known whether removing these normal-looking lymph nodes actually improves long-term survival. This uncertainty is the reason this research study is being conducted.

Your treating team will always act in your best interest. If enlarged or suspicious lymph nodes are identified during surgery, they will be removed irrespective of the treatment group assigned to you.

If any new information becomes available during the course of the study that may influence your willingness to continue participation, you will be informed promptly.

9. Appropriate alternative approaches / procedures

Participation in this study is entirely voluntary. If you choose not to participate, you will receive the standard treatment recommended by your treating team. Your doctor will decide the most appropriate surgical procedure based on current institutional practice and existing treatment guidelines. Refusing participation will not affect your medical care, relationship with your treating doctors, or any future treatment at this hospital.

10. Are there other reasons why I might stop being in the study?

Yes.

The study doctor may withdraw you from the study if:

- Your disease is found to be more advanced than initially suspected.
- The frozen section diagnosis does not confirm high-grade epithelial ovarian cancer.
- Suspicious lymph nodes or extensive disease requiring treatment outside the study protocol are identified.
- New medical information suggests that continuing in the study is not in your best interest.
- The study is stopped by the Institutional Ethics Committee, regulatory authorities, or the study sponsor.

11. If I decide to take part in this study, can I stop later?

Yes.

Your participation is completely voluntary.

You may withdraw your consent at any time without giving any reason. Your decision will not affect your medical care, treatment, or relationship with your treating doctors. Data already collected before withdrawal may continue to be used in an anonymized form unless prohibited by applicable regulations.

12. Will I receive payment for taking part in this study?

You will not be paid for taking part in this study.

13. What are the costs of taking part in this study?

Participation in this study will not result in any additional financial burden beyond the routine costs associated with your standard treatment for ovarian cancer.

14. What happens if I am injured or hurt because I took part in this study?

Every effort will be made to ensure your safety during the study. If you suffer any research-related injury, you will receive appropriate medical treatment according to the applicable ICMR guidelines and institutional policies. Participation in this study does not affect your legal rights. If you believe you have suffered an injury related to participation in this study, you should immediately inform the study investigator.

15. Confidentiality of your information

All information collected during this study will be kept strictly confidential.

Your identity will be replaced by a unique study identification number. Only authorized members of the research team, Institutional Ethics Committee, regulatory authorities, study monitors, or auditors may review your medical records if required.

The results of this study may be published in scientific journals or presented at conferences; however, your identity will never be disclosed. Data collected during this study may be shared with collaborating institutions after removal of all personal identifiers.

16. What will happen to the results of this study?

The results of this study will be analyzed and may be published in national or international scientific journals or presented at scientific meetings.

Participants will not be identified in any publication or presentation.

The findings from this study may contribute to improving future treatment guidelines for women with ovarian cancer.

17. There are **no known investigator and/or institutional conflicts of interest** for this study.

18. Contact Information

For questions or concerns, you can contact the study investigators at Tata Medical Center, Kolkata.

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INFORMED CONSENT FORM (English)

Title of the project:

A Phase III Randomized Trial of Systematic Lymphadenectomy in Patients with Apparent Early-Stage Epithelial Ovarian Cancer (ROSE Trial)

Participant's name:

Address:

1. Understanding the Study: I have been given written information about this study, and it has also been explained to me in my own language. I confirm that I understand the purpose of this study, the procedures involved, and my role in it. I have had the chance to ask questions, and all my questions have been answered.

2. Risks and Benefits: I understand the possible risks and benefits of participating in this study.

3. Voluntary Participation: I understand that my participation in this study is completely voluntary. I can choose to withdraw from the study at any time, without giving any reason. My decision to leave the study will not affect my routine medical care at this hospital in any way.

4. Confidentiality: I understand that my personal information will be kept private during the study, after the study ends, and even during the publication of the results. I understand that only the investigator, ethics committee, or regulatory authorities will have access to my information, if needed.

5. My Consent: I have been given a copy of the information sheet with all the details of the study. I volunteer to participate in this study.

"Risk and benefit of this project has been explained to me"

Signature/thumb impression of the participant: _____

Name of the participant: _____

Date: _____

Signature of the witness: _____ Date: _____

Name and address of the witness for illiterate participants:

Signature of the investigator: _____ Date: _____

Name of the investigator: _____ Date: _____



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