

ROSE TRIAL

ELECTRONIC CASE REPORT FORM (eCRF)

A Phase III Randomized Trial of Systematic Lymphadenectomy in Patients with Apparent Early-Stage
High Grade Epithelial Ovarian Cancer

Protocol ID: ROSE eCRF Version: 3.0 Date: 25 August 2026

Coordinating Centre: Tata Medical Center, Kolkata



Section 1 – Screening and Informed Consent

Study Identification Number _____

Centre / Site _____

Date of screening ____ / ____ / ____

Clinically suspected early stage ovarian cancer

Screening criteria A

1. Clinically palpable suspected adnexal mass ☐ Yes ☐ No
2. Ultrasound scan diagnosed adnexal mass ☐ Yes ☐ No
3. Outside operated, but unstaged/biopsied/FNAC suggestive high-grade EOC ☐ Yes ☐ No

[Previous histology or cytology proof is not necessary for inclusion in this study]

If anyone of these answers is 'Yes', go for screening criteria B

Screening criteria B

Cross sectional image (CECT/MRI/PET-CT)

1. Cross sectional image suggesting extra-ovarian disease
 - a. Peritoneal ☐ Yes ☐ No
 - b. Lymph nodal ☐ Yes ☐ No
 - c. Extra-abdominal ☐ Yes ☐ No

All answers to be 'No' to be eligible for the study

If eligible from the above criteria

Screening criteria C

1. Is the patient unfit for surgery? (ECOG 3 or more) ☐ Yes ☐ No
2. Is the patient unfit for surgery because of serious comorbidities? ☐ Yes ☐ No
3. Is the patient less than 18 years of age? ☐ Yes ☐ No
4. Is the patient incapable of giving informed consent? ☐ Yes ☐ No

Counsel the patient for participating in the study if all the answers to the above questions is 'No'.

Screening outcome ☐ Screen failure ☐ Proceed to counselling for recruitment

Primary reason for screen failure _____

Other reason / comments _____

Written informed consent obtained ☐ Yes ☐ No

Date of consent ____ / ____ / ____

Person obtaining consent (name / staff ID) _____

Section 2 – Baseline Demographics and Medical History

Age at enrolment _____ years

Menopausal status ☐ Pre-menopausal ☐ Post-menopausal

Parity _____

Height _____ cm

Weight _____ kg

BMI _____ kg/m²

ECOG performance status ☐ 0 ☐ 1 ☐ 2

Relevant presenting symptoms _____

Duration of symptoms _____

Comorbidities ☐ No ☐ Yes

Comorbidities ☐ Hypertension ☐ Diabetes ☐ Cardiovascular ☐ Respiratory ☐ Renal ☐

Hypothyroidism ☐ Other: _____

Previous abdomino-pelvic surgery ☐ No ☐ Yes

Details _____

Previous personal history of cancer ☐ No ☐ Yes

If yes – site / year / treatment _____

Current medication ☐ None ☐ Yes

Details _____

Drug / other allergy ☐ No ☐ Yes

Details _____

Family history of cancer ☐ No ☐ Yes

Details _____

Pregnancy / lactation ☐ No ☐ Yes ☐ Not applicable

Other relevant medical history _____

Section 3 – Baseline Clinical Assessment

Date of clinical assessment ____ / ____ / ____

Clinically palpable / suspected pelvic mass ☐ Yes ☐ No

Clinical ascites ☐ No ☐ Yes

Estimated / measured ascites volume, if available _____ mL

Relevant abdominal / pelvic findings _____

Other clinical findings relevant to eligibility _____

Section 4 – Baseline Laboratory Investigations

Investigation	Date	Result	Within protocol requirement
Haemoglobin	____/____/____	_____	☐ Yes ☐ No
WBC	____/____/____	_____	☐ Yes ☐ No
Platelets	____/____/____	_____	☐ Yes ☐ No
Creatinine / renal function	____/____/____	_____	☐ Yes ☐ No
AST / ALT / bilirubin / Albumin	____/____/____	_____	☐ Yes ☐ No
CA-125	____/____/____	_____	—
CEA	____/____/____	_____	—
CA19-9	____/____/____	_____	—
CA-125 / CEA ratio	____/____/____	_____	☐ >25 ☐ ≤25
Other clinically indicated test	____/____/____	_____	_____

If CA-125/CEA ratio ≤25 ☐ GI evaluation performed ☐ GI primary excluded ☐ Not applicable

Type/date of GI evaluation, if applicable _____

Section 5 – Baseline Radiological Assessment

Imaging modality ☐ CECT ☐ MRI ☐ PET-CT ☐ Other

Imaging date ____ / ____ / ____

Tumour / mass size _____ cm

Laterality ☐ Right ☐ Left ☐ Bilateral ☐ Indeterminate

Extra-pelvic peritoneal tumour implants on imaging ☐ Absent ☐ Present ☐ Indeterminate

Suspicious / enlarged pelvic lymph nodes ☐ Absent ☐ Present ☐ Indeterminate

Largest pelvic node short-axis, if present _____ mm

Suspicious / enlarged para-aortic lymph nodes ☐ Absent ☐ Present ☐ Indeterminate

Largest para-aortic node short-axis, if present _____ mm

Radiological ascites ☐ Absent ☐ Present

Ascites volume, if reported _____ mL

Other relevant radiological findings _____

Preoperative radiological assessment ☐ Compatible with apparent early-stage disease ☐ Not compatible

Section 6 – Preoperative Eligibility Assessment

6A. Preoperative Inclusion Criteria

Preoperative inclusion criterion	Status
1. Age ≥ 18 years	☐ Yes ☐ No
2. Clinically and radiologically confirmed pelvic mass arising from single or both adnexa	☐ Yes ☐ No
3. No extra-pelvic peritoneal tumour implants on preoperative imaging	☐ Yes ☐ No
4. No enlarged/suspicious pelvic or para-aortic lymph nodes on preoperative imaging	☐ Yes ☐ No
5. CA-125/CEA ratio >25 ; if ≤ 25 , digestive tract primary appropriately excluded	☐ Yes ☐ No ☐ N/A
6. ECOG performance status 0–2	☐ Yes ☐ No
7. Adequate organ function on standard preoperative laboratory assessment	☐ Yes ☐ No

8. Written informed consent, including consent for intraoperative randomisation	☐ Yes ☐ No
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6B. Preoperative Exclusion Criteria

Preoperative exclusion criterion	Status
1. Concurrent malignancy or history of another malignancy within previous 5 years	☐ Absent ☐ Present
2. Previous retroperitoneal lymph-node dissection	☐ Absent ☐ Present
3. Pregnancy or lactation	☐ Absent ☐ Present ☐ N/A
4. Serious medical comorbidity precluding major surgery	☐ Absent ☐ Present
5. Inability to comply with study protocol or follow-up requirements	☐ No ☐ Yes

Preoperative eligibility status ☐ Eligible to proceed to surgery / intraoperative assessment ☐ Not eligible

Date ____ / ____ / ____

Reason if not eligible _____

Section 7 – Intraoperative Eligibility Confirmation

Date of surgery ____ / ____ / ____

Operative approach at start of procedure ☐ Open ☐ Laparoscopic ☐ Robotic

Frozen section diagnosis _____

Frozen section diagnosis compatible with high-grade epithelial ovarian carcinoma ☐ Yes ☐ No

Intraoperative extra-adnexal macroscopic disease ☐ Absent ☐ Present

If present, mention site _____

Suspicious / enlarged pelvic lymph nodes ☐ Absent ☐ Present

Suspicious / enlarged para-aortic lymph nodes ☐ Absent ☐ Present

Other intraoperative finding affecting eligibility _____

Apparent early-stage disease confirmed intraoperatively ☐ Yes ☐ No

Final eligibility for randomisation ☐ Eligible ☐ Not eligible

If not eligible – reason _____

Section 8 – Randomisation

Randomisation number _____

Date / time of randomisation ____ / ____ / ____ ____:____

Treatment allocation

☐ Arm A – Systematic pelvic + para-aortic lymphadenectomy

☐ Arm B – No systematic pelvic + para-aortic lymphadenectomy

Randomisation completed ☐ Yes ☐ No

Section 9 – Surgical Findings and Operative Details

Tumour laterality ☐ Right ☐ Left ☐ Bilateral

Capsule rupture ☐ No ☐ Yes

Ascites volume _____ mL

Suspicious but not enlarged pelvic lymph nodes ☐ Absent ☐ Present

Suspicious but not enlarged para-aortic lymph nodes ☐ Absent ☐ Present

Incision time _____ (24hour clock)

Last suture / staple time _____ (24hour clock)

Operative duration _____ minutes

Estimated blood loss _____ mL

Intraoperative blood transfusion ☐ No ☐ Yes

Units transfused _____

Intraoperative complication ☐ No ☐ Yes

Conversion to laparotomy ☐ No ☐ Yes ☐ Not applicable

Reason for conversion _____

Protocol compliance with allocated arm ☐ Yes ☐ No

Reason for non-compliance / deviation _____

Section 10 – Surgical Staging and Lymphadenectomy

Peritoneal washings ☐ Performed ☐ Not performed

Total hysterectomy ☐ Performed ☐ Not performed

Bilateral salpingo-oophorectomy ☐ Performed ☐ USO only

Omentectomy ☐ Infra-colic ☐ Total

Random peritoneal biopsies ☐ Performed ☐ Not performed

Other staging procedure _____

Lymphadenectomy

Systematic pelvic lymphadenectomy ☐ Performed ☐ Not performed

Systematic para-aortic lymphadenectomy ☐ Performed ☐ Not performed

Selective removal of suspicious/enlarged nodes in Arm B ☐ No ☐ Yes ☐ Not applicable

Site of selectively removed nodes _____

Section 11 – Postoperative Recovery and 30-Day Outcomes

Date of discharge ____ / ____ / ____

Length of hospital stay _____ days

ICU admission ☐ No ☐ Yes

ICU stay _____ days

Postoperative complication within 30 days ☐ No ☐ Yes

Highest Clavien–Dindo grade ☐ I ☐ II ☐ IIIa ☐ IIIb ☐ IVa ☐ IVb ☐ V

30-day readmission ☐ No ☐ Yes

30-day reoperation ☐ No ☐ Yes

30-day mortality ☐ No ☐ Yes

Date of death, if applicable ____ / ____ / ____

Complication categories: Intra-Op

Bleeding / transfusion-related complication ☐ No ☐ Yes

Vascular injury ☐ No ☐ Yes

Nerve injury ☐ No ☐ Yes

Urinary tract injury ☐ No ☐ Yes

Bowel injury / complication ☐ No ☐ Yes

Anaesthetic complication ☐ No ☐ Yes

Complication categories: Post-Op

Post operative bleeding ☐ No ☐ Yes

Ileus ☐ No ☐ Yes

UTI ☐ No ☐ Yes

Pneumonia ☐ No ☐ Yes

Lymphorrhagia ☐ No ☐ Yes

Chylous ascites ☐ No ☐ Yes

Surgical-site infection / wound complication ☐ No ☐ Yes

Pelvic/Deep space infection ☐ No ☐ Yes

Vaginal cuff infection ☐ No ☐ Yes

Vaginal cuff dehiscence ☐ No ☐ Yes

Thromboembolic event ☐ No ☐ Yes

Readmission to ICU ☐ No ☐ Yes

Re-intervention ☐ No ☐ Yes

Other clinically significant complication ☐ No ☐ Yes

Section 12 – Final Histopathology

Histological subtype _____

Tumour grade _____

Tumour size _____ cm

Laterality ☐ Right ☐ Left ☐ Bilateral

Capsule ☐ Intact ☐ Ruptured

Ovarian surface involvement ☐ No ☐ Yes

Fallopian tube involvement ☐ No ☐ Yes

Peritoneal cytology ☐ Negative ☐ Positive ☐ Not done

Omental involvement ☐ No ☐ Yes

Peritoneal biopsy involvement ☐ No ☐ Yes

Other relevant pathology _____

Lymph Node Pathology

Pelvic nodes examined _____

Pelvic nodes positive _____

Para-aortic nodes examined _____

Para-aortic nodes positive _____

Final FIGO stage _____

Final pathological stage _____

Pathology report date ____ / ____ / ____

Section 13 – Adjuvant Treatment

Adjuvant chemotherapy indicated ☐ Yes ☐ No

Indication _____

Regimen _____

Start date ____ / ____ / ____

Cycles planned _____

Cycles received _____

Days from surgery to chemotherapy initiation _____ days

Treatment start delay > 6 weeks ☐ No ☐ Yes

Reason if yes _____

Dose reduction ☐ No ☐ Yes

Reason if yes _____

Adjuvant treatment prolonged beyond 6 calendar months ☐ No ☐ Yes

Reason if yes _____

Treatment discontinued ☐ No ☐ Yes

Reason if yes _____

Treatment completed ☐ Yes ☐ No

Date completed ____ / ____ / ____

Stratification Variables

Factor	Category / value
FIGO stage	_____
Histological type	_____
Participating centre	_____
Adjuvant chemotherapy	☐ Yes ☐ No

Section 14 – Health-Related Quality of Life and PROMs

14A. FACT-O

FACT-O completed ☐ Yes ☐ No

Assessment timepoint ☐ Baseline ☐ 30 days ☐ 12 months

Assessment date ____ / ____ / ____

Score / database entry _____

14B. Lymphedema-specific PROM / GCLQ-7

GCLQ-7 completed ☐ Yes ☐ No

Assessment timepoint ☐ Baseline ☐ 30 days ☐ 12 months

Assessment date ____ / ____ / ____

GCLQ-7 total score _____

Section 15 – Follow-up and Disease Status

Follow-up dates ____ / ____ / _____, ...

Tumour markers Normal/abnormal (more than twice the previous value)

Follow up scan ☐ Yes ☐ No

Any event ☐ Yes ☐ No

If yes to above

Date of event

Type of event

ECOG performance status _____

CA-125 _____

Imaging performed ☐ No ☐ Yes

Imaging modality / result _____

Recurrence ☐ No ☐ Yes

Date of recurrence ____ / ____ / ____

First recurrence pattern/site ☐ Extra-abdominal ☐ Peritoneal ☐ Nodal ☐ Multiple ☐ Other

Specific site _____

Histopathological confirmation ☐ No ☐ Yes ☐ Not applicable

Date confirmed ____ / ____ / ____

Treatment for recurrence Surgery/Surgery+Chemo/Only Chemo

Date treatment started ____ / ____ / ____

Survival status at data analysis

Alive without disease/ Alive with disease/Dead/Unknown

Cause of death, if applicable _____

Section 17 – Adverse Events and Serious Adverse Events

Any AE during reporting period ☐ No ☐ Yes

Any SAE during reporting period ☐ No ☐ Yes

SAE report submitted ☐ Yes ☐ No ☐ Not applicable

Related to allocated intervention / trial-related procedure ☐ Yes ☐ No ☐ Uncertain

30-day postoperative SAE ☐ No ☐ Yes

Section 18 – Protocol Deviations and Arm Compliance

Protocol deviation ☐ No ☐ Yes

Date identified ____ / ____ / ____

Type / reason _____

Deviation classification ☐ Major ☐ Minor

Allocated treatment arm followed ☐ Yes ☐ No

Reason for deviation _____

Corrective action / comments _____

Section 19 – Investigator / Data Entry Declaration

I certify that the information recorded in this eCRF is accurate and complete to the best of my knowledge and has been entered prospectively in accordance with the ROSE trial protocol and applicable study procedures.

Name of investigator / authorised study staff _____

Designation _____

Centre _____

Signature / electronic confirmation _____

Date ____ / ____ / ____

eCRF completion date ____ / ____ / ____