FAST FACTS

NRG CC008 - A Non-Randomized Prospective Clinical Trial Comparing the Non-Inferiority of Salpingectomy to Salpingo-Oophorectomy to Reduce the Risk of Ovarian Cancer Among BRCA1 Carriers [SOROCk]

3.1 Eligibility Criteria

A patient cannot be considered eligible for this study unless ALL of the following conditions are met.

3.1.1 Individuals 35-50 years of age, inclusive.

3.1.2 Patients who will undergo RRSO (for the BSO arm) and patients who have declined or elected to defer BSO after proper counselling to clearly explain the standard of care for *BRCA1* mutation carriers and are undergoing salpingectomy (for the BLS arm with delayed oophorectomy arm) . Concurrently planned hysterectomy with either arm is permitted.

3.1.3 At least one intact ovary and fallopian tube is in situ at the time of counseling, consent, and registration. Prior hysterectomy is allowed provided it did not include bilateral salpingectomy**.** Prior tubal ligation is allowed if one ovary and fallopian tube (with fimbria not removed) are present.

3.1.4 Positive CLIA-approved test results for pathogenic or likely pathogenic germline *BRCA1* mutation in the patient. Documentation of the result is required.

3.1.5 Patients may be premenopausal or menopausal.

3.1.6 Pelvic ultrasound (transvaginal imaging preferred, but transabdominal imaging is acceptable) or pelvic MRI and CA-125 within 180 days of registration.

3.1.7 The patient or a legally authorized representative must provide study-specific informed consent prior to study entry.

3.1.8 Individuals who are currently pregnant or plan to become pregnant in the future through assisted reproductive technologies and who have received proper counseling are eligible. Individuals who are currently pregnant and plan bilateral salpingectomy at the time of a planned cesarean section are eligible. Patients must understand that they will not be able to become pregnant naturally in the future.

3.2 Ineligibility Criteria

Patients with any of the following conditions are NOT eligible for this study.

3.2.1 Individuals with a history of any prior cancer who have received cytotoxic chemotherapy within the past 30 days or radiotherapy to abdomen or pelvis at any prior time. Endocrine therapy or maintenance *ERBB2/HER2*-targeted therapy is allowed. Maintenance immune checkpoint inhibitor therapy is allowed. Maintenance therapy with PARP in inhibitor is allowed.

3.2.2 Prior history of ovarian cancer, including low malignant potential neoplasms (LMP), primary peritoneal carcinoma, or fallopian tube carcinoma.

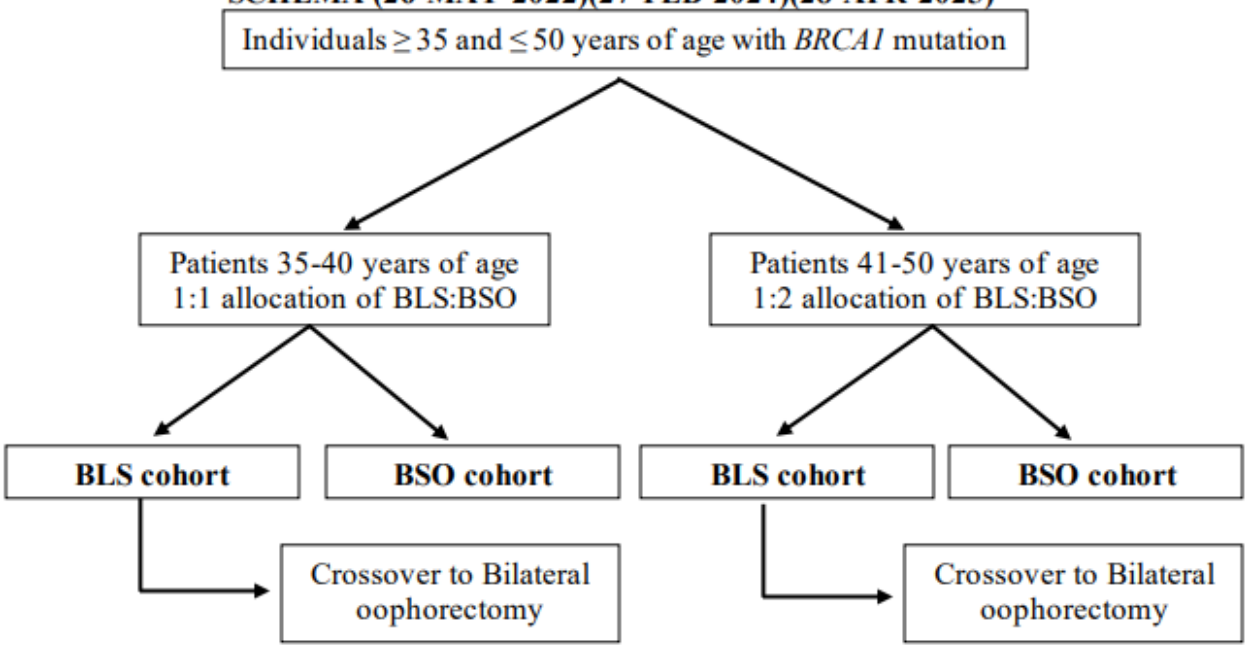
3.2.3 Patients medically unfit for the planned surgical procedure.

3.2.4 Patients with abnormal screening tests (pelvic ultrasound, pelvic MRI, CA-125) suspicious for occult or gross pelvic malignancy within the past 180 days.

a) An abnormal pelvic ultrasound (or pelvic MRI) is defined as morphologic or structural variations suspicious for ovarian malignancy. Complex cystic lesions felt to represent a benign lesion are not exclusionary. Simple cysts of any size are not exclusionary.

b) An abnormal CA-125 is defined as a level >50U/ml in premenopausal individuals if they are not current users of oral contraceptives; an abnormal CA-125 is defined as a level >40U/ml for premenopausal individuals who are current users of oral contraceptives (Skates 2011). An abnormal CA-125 is defined as a level >35 U/ml in postmenopausal individuals

NRG-CC008
SCHEMA (26-MAY-2022)(27-FEB-2024)(28-APR-2025)



***BLS**-bilaterally salpingectomy, **BSO**-bilateral salpingo-oophorectomy*