EROS: Engendering Reproductive Health Within Oncologic Survivorship

Overall E1Q11 Study Objective

To examine an intervention of a reproductive health assessment and algorithm to improve the adoption of appropriate reproductive health management

Study Schema

Eligibility Criteria*

- Female and presenting with initial diagnosis of any type of cancer, including ductal carcinoma in situ (DCIS)
- Premenopausal within the reproductive age of 15-55 years
- Premenopausal criteria include the following: not currently on hormonal contraception with menses in the past 6 months; no menses in the past 6 months without hormonal manipulation, and confirmed follicle-stimulating hormone (FSH) < 23 mIU/mL; age < 47 years and on hormonal contraception; age ≥ 47 years and on hormonal contraception with confirmed FSH < 23 mIU/mL
- No chemotherapy, radiation therapy, or endocrine therapy initiated prior to study registration
- No prior hysterectomy, bilateral oophorectomy, or sterilization of any method
- Pregnant females are eligible
- Cognitive ability to participate in the trial

*When evaluating patients for this study, please refer to the full protocol for the complete list of eligibility criteria.
Study Objectives

Primary Objective
- Evaluate the success of the implementation of reproductive health programming (Didactics, EROS Reproductive Health Assessment, and EROS Trial Algorithm) among reproductive-aged females (15-55 y) with cancer

Secondary Objectives
- Assess the degree of discrepancy between patients and clinicians in their estimates of the significance of reproductive health goals for the patient
- Identify clinical and demographic factors that predict the adequacy of reproductive health care management
- Evaluate baseline and follow-up reproductive health assessments for trends in reproductive health choices relating to oncofertility, oncocontraception, and pregnancy over the 2-year study period

Correlative Objective
- Perform a longitudinal study following endocrine markers of fertility in a cohort of the first 200 registered EROS trial patients who agree to participate

Quality of Life Objective
- Perform a longitudinal study of sexual function using the PROMIS sexual function survey in all subjects participating in the EROS trial

On-Site and Study Assessment Timelines

Site Specific

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*More steps are required for intervention arm B. CIRB = Central Institutional Review Board.

Subject Specific

| Recruitment Time Frame | Patient Recruitment 1. CRA/CRN approach: preliminarily eligible patient to determine interest 2. If interested, confirm eligibility | Patient Baseline* 1. Consent signed 2. Baseline visit with provider 3. Baseline surveys completed after visit 4. Patient registered | 3-month visit | 6-month visit | 12-month visit | 24-month visit |

*Baseline provider visit, baseline surveys, and registration should be completed on the same day as consent. If this is not feasible, baseline visit, baseline forms, and registration must be completed on the same day, within 1 week of consent and before treatment initiation. CRA = clinical research associate; CRN = clinical research nurse.

For Further Information

- For more information about the E1Q11 study, please visit Clinicaltrials.gov; search NCT01806129
- For more information about ECOG-ACRIN, visit ecog-acrin.org