

## FAST FACTS

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**S1904** - CLUSTER RANDOMIZED CONTROLLED TRIAL OF PATIENT AND PROVIDER DECISION SUPPORT TO INCREASE CHEMOPREVENTION INFORMED CHOICE AMONG WOMEN WITH ATYPICAL HYPERPLASIA OR LOBULAR CARCINOMA *IN SITU* - MAKING INFORMED CHOICES ON INCORPORATING CHEMOPREVENTION INTO CARE (MiCHOICE)

### Eligibility Criteria

#### Disease Related Criteria for Patients

1. Patients must have histologically-confirmed atypical hyperplasia (AH) or lobular carcinoma *in situ* (LCIS) documented by breast pathology report at any time in the past. Patients with borderline breast lesions and pleomorphic LCIS are also eligible as long as the pathology is considered benign.
2. Patients must not have a history of invasive breast cancer or ductal *carcinoma in situ*.
3. No other prior malignancy is allowed except for adequately treated basal cell (or squamous cell) skin cancer, in situ cervical cancer or other cancer for which the patient has been disease free for at least five years.

#### Prior/Concurrent Therapy Criteria for Patients

1. Patients must not have prior or current use of selective estrogen receptor modulators (SERMs) or aromatase inhibitors (AIs). Examples of such therapy include, but are not limited to: tamoxifen, raloxifene, anastrozole, exemestane.  
NOTE: Patients who have had prior topical tamoxifen are eligible. Patients who have had prior oral SERM or AI are NOT eligible.
2. Patients must not be currently taking systemic hormone replacement therapy.
3. NOTE: Patients who are currently using topical/vaginal estrogen are eligible. Examples of such therapy include but are not limited to: Premarin®, Estrace®, Vagifem®, Estradiol, and Divigel®.
4. Patients who are co-enrolled in other chemoprevention trials must not have started on an oral SERM or AI at the time of registration to **S1904**.

#### Clinical/Laboratory Criteria for Patients

1. Patients must be women at least 35 and no more than 74 years of age at registration, since the Breast Cancer Surveillance Consortium (BCSC) risk calculator is valid only for this age range.
2. Patients must not have a history of bilateral mastectomies or breast implants since the risk calculator is not applicable to these women.
3. Both pre/perimenopausal and postmenopausal women are eligible.
4. Patients must not be pregnant or lactating.
5. Premenopausal patients must not have a history of thromboembolism, since it is a contraindication to tamoxifen. Tamoxifen is the only FDA-approved drug for breast cancer chemoprevention among high-risk premenopausal women, whereas postmenopausal women are eligible for both SERMs and AIs.
6. Patients must be able to read and write in English or Spanish since study questionnaires and educational materials are only available in English and Spanish.
7. Baseline questionnaires must be completed prior to patient registration.
8. The **S1904** Patient Contact form must be completed prior to patient registration.
9. Patients must be able to access the internet and receive phone calls, emails or text messages. This is required to access study materials, to receive email/text message reminders from the **S1904** Study Team at CUIMC, and to complete a tutorial of the *RealRisks* tool via phone or video-conference with the **S1904** Study Team at CUIMC. The patient decision aid, *RealRisks*, is

accessible via smartphones, tablets, or personal computers. If patients do not own these devices, local study personnel will provide resources for patients to access *RealRisks* via computer kiosks or tablets in clinic waiting rooms or public locations, such as community centers or public libraries.

