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Protocol No. HCI IRB # 100288

Comparison of Operative to Monitoring and Endocrine Therapy (COMET) Trial for Low Risk DCIS: A Phase III Prospective Randomized Trial

Objectives

To study the risks and benefits of active surveillance (AS) compared to guideline concordant care (GCC) in the setting of a pragmatic prospective randomized trial for low risk DCIS. Our overarching hypothesis is that management of low-risk DCIS using an AS approach does not yield inferior cancer or quality of life outcomes compared to GCC.

Primary Objective:

To assess whether 2-year ipsilateral invasive cancer rate for AS is non-inferior to that for GCC.

Secondary Objectives:

To determine whether AS is non-inferior to GCC for the following outcomes: 2-year mastectomy rate, breast conservation rate; 2-year contralateral invasive breast cancer rate; 2-year overall survival and breast cancer specific survival; health-related QOL at 1 year, 2 years; anxiety and depression and other psychosocial outcomes at 1 year, 2 years

Inclusion Criteria

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New diagnosis of DCIS without invasive cancer. Unilateral, bilateral, unifocal, or multifocal DCIS will be eligible, provided that all DCIS meets eligibility criteria

No prior history of breast cancer (DCIS or invasive cancer) in either breast

Age >= 40 at time of DCIS diagnosis

ECOG performance status 0 or 1

No contraindication for surgery

Bilateral mammogram within 6 months of registration; ipsilateral breast imaging within 90 days of registration (can include mammogram, ultrasound, or breast MRI)

Pathologic diagnosis of DCIS within 90 days of registration:

Histology slides reviewed and diagnosis confirmed by concordance among two clinical pathologists

Grade I/II DCIS without invasion or microinvasion

Diagnosis confirmed on core needle biopsy or surgical biopsy within 90 days of registration

ER(+) and/or PR(+) by IHC (>= 10% staining or Allred score >= 4)

HER2 0, 1+, or 2+ by IHC if HER2 testing is performed

Absence of comedonecrosis

At least two sites of biopsy for those cases where mammographic extent of calcifications exceeds 4 cm, both sites fulfilling eligibility criteria for DCIS without invasion or microinvasion

Amenable to follow up examinations

Ability to read, understand and evaluate study materials and willingness to sign a written informed consent document

Reads and speaks Spanish or English, or availability of an appropriate professional interpreter at enrollment

Inclusion of Women and Minorities

Women of all races and ethnic groups are eligible for this trial.

Exclusion Criteria

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Male DCIS

Concurrent diagnosis of invasive breast cancer in either breast, including microinvasion

Mass on examination or imaging at site of DCIS prior to biopsy yielding diagnosis of DCIS

Bloody nipple discharge

Mammographic finding of BIRADS 4 or greater at site other than that of known DCIS within 6 months of registration

Use of investigational cancer agents within 6 weeks prior to diagnosis

Any serious and/or unstable pre-existing medical, psychiatric, or other existing condition that would prevent compliance with the trial or consent process

Pregnancy

Documented history of prior tamoxifen, aromatase inhibitor or raloxifene

This posting is a summary of the basic requirements for participation in this study, and it is not intended to provide all the information needed to decide whether or not to participate.

For additional information on all aspects of cancer, please contact the Huntsman Cancer Institute Information Service at the phone numbers listed below.

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