

ASHBY: Accelerated Super-Hypofractionated Breast Brachytherapy

Status: RECRUITING

Eligibility Criteria

Age: 45 years to 79 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Female * New diagnosis of ductal carcinoma in situ (DCIS) and/or invasive breast carcinoma per histologic evaluation * Age 45-79 at diagnosis * Previous lumpectomy with surgical margins histologically free of invasive tumor and DCIS as determined by the pathologist. * T stage of Tis, T1, or T2. * T2 tumors must be ≤ 3 cm in maximum diameter * If the tumor is human epidermal growth factor receptor 2 (HER2)-positive, the patient must receive HER2-directed therapy. * For patients with invasive breast cancer, an axillary staging procedure must be performed (either sentinel node biopsy alone or axillary dissection \[with a minimum of 6 axillary nodes removed\]) and the axillary node\[s\] must be pathologically negative. * Note: N0(i+) is not an exclusion criterion. * Note: Patients meeting all of the following criteria are not required to undergo the axillary staging procedure: * ≥ 70 years of age * estrogen receptor, Her2 = human epidermal growth factor receptor 2, PR = progesterone receptor negative (ER+PR+HER2-) * G1-2 * Tumor ≤ 2 cm in size * Agrees to comply with aromatase inhibitor recommendation * Ability to understand and the willingness to sign a written informed consent document in English

Exclusion Criteria:

* Pregnant or breastfeeding * Active collagen-vascular disease * Paget's disease of the breast * History of DCIS or invasive breast cancer prior to the current diagnosis * Prior breast or thoracic radiation therapy (RT) for any condition * Multicentric carcinoma (DCIS or invasive) * Synchronous bilateral invasive or non-invasive breast cancer * Surgical margins that cannot be microscopically assessed or that are positive * Excision cavity that cannot be clearly delineated per the treating investigator * Any of the dosimetric treatment criteria defined in Section 6.1 have not been met. Patients who become ineligible due to inability to meet dosimetric criteria should not receive treatment as

•defined in this protocol and will come off the study. Any subsequent adjuvant radiation will be delivered at the discretion of the treating physician * Medical, psychological, or social condition that, in the opinion of the investigator, may increase the patient's risk or limit the patient's adherence with study requirements

Conditions & Interventions

Interventions:

DRUG: Accelerated partial breast irradiation

Conditions:

Breast Cancer

Keywords:

Breast Cancer, Ductal Carcinoma in situ (DCIS), Irradiation

More Information

Contact(s): Massey IIT Research Operations - masseyepd@vcu.edu

Principal Investigator:

Phase: PHASE2

IRB

Number:

System ID: NCT06185205

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