Breast cancer patient suitable for breast conserving therapy

NO RANDOMIZATION

Study Arm

Wide local excision of primary tumor
+ definitive sentinel node biopsy
+ IORT

Pathology shows

- No adverse criteria
- Invasive lobular or Extensive intraductal component or Adverse criteria
- Involved margins

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<th>No further local treatment</th>
<th>Whole breast radiotherapy omitting the tumor bed boost</th>
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<td>Re-excise to clear margins</td>
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Regular Follow-up
Eligible patients: Cohorts 1 and 2
- Female
- Age 45 years old or older with operable invasive breast cancer
- T1 and T2 (<3.5 cm), N0, M0, confirmed by clinical, cytological or histological examination
- Suitable for breast conserving surgery and radiotherapy
- Ipsilateral diagnostic mammogram within 12 months of enrollment

Those with previously diagnosed and treated contralateral breast cancer may be entered. It is recommended that patients meet an ECOG performance status of 0-3, however, grade 4 patients can be treated at the discretion of the participating center. Individual centers may wish to restrict entry to a more exactly defined subset of patients in which case only patients with these characteristics may be entered by the particular center. For example, centers may decide at outset to recruit only women over the age of 50 or possibly only postmenopausal women. Such policies must be predefined in writing on the Treatment Policy Statement form, submitted and approved by the Steering Committee, and followed for all patients enrolled at that center. See section 6.1.

Before entering any patient into the trial, the local investigator should confirm that the patient would be available for regular follow-up for at least 5 years.

Exclusion criteria
All Cohorts:
- Age < 45 years
- Known axillary lymph node positive breast cancer (FNA not required)
- Invasive lobular cancer
- Tumor size > 3.5 cm
- Multicentric cancer in the same breast as diagnosed by clinical examination, mammography, ultrasound. MRI or pathologic assessment, not amenable to excision with negative margins with a single lumpectomy.
- Synchronous bilateral breast cancer at the time of diagnosis.
- Ipsilateral breast had a previous cancer and/or prior in-field radiation.
- Patients known to have BRCA1/2 gene mutations (testing for gene mutations is not required).
- Patients undergoing primary systemic treatment (hormones or chemotherapy) as initial treatment with neoadjuvant intent of reducing tumor size.
- Previous history of malignant disease does not preclude entry if the expectation of relapse-free survival at 10 years is 75% or greater
- Any factor included as exclusion criteria in the participating center’s Treatment Policy Statement.