Cancer Research Consortium of West Michigan
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FAST FACTS

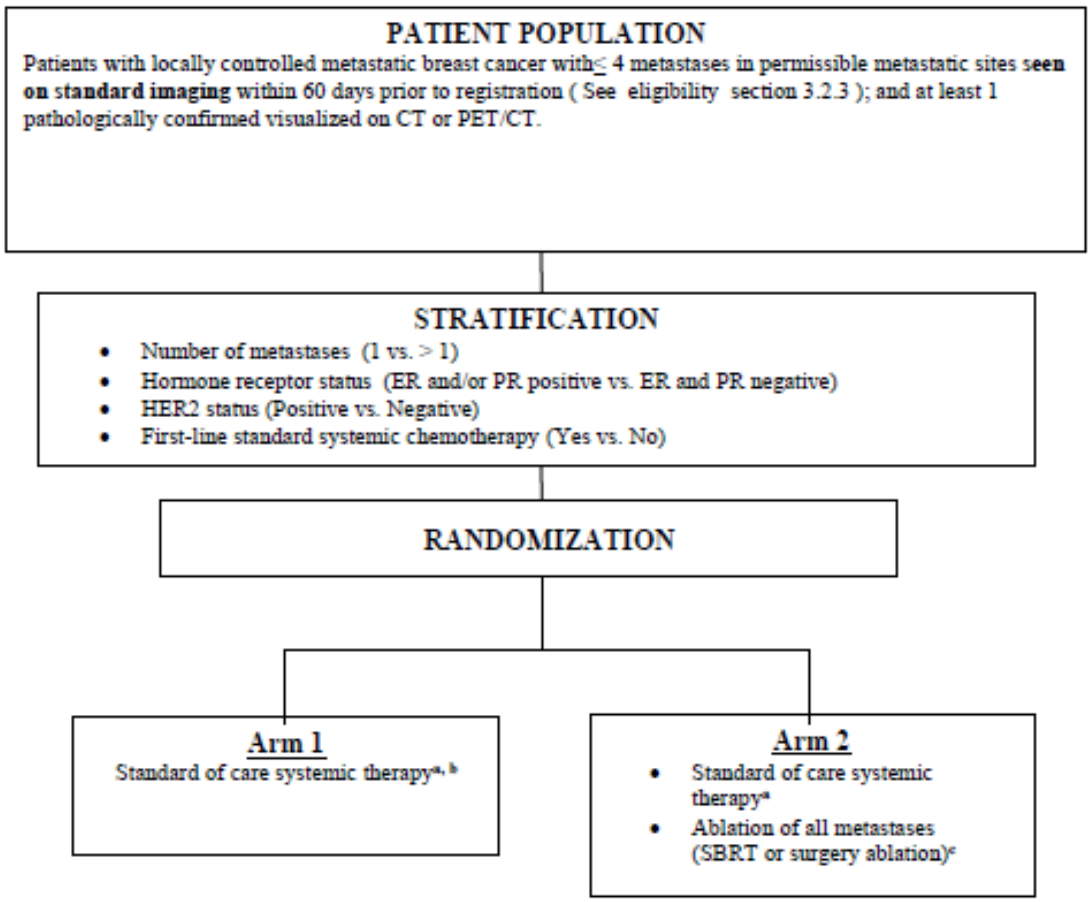
NRG -BR002 - A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer

ELIGIBILITY CRITERIA

1. Pathologically confirmed metastatic breast cancer
2. Known estrogen, progesterone, and HER2 status of either primary tumor or metastasis; Note: estrogen**,** progesterone and HER2 status of metastasis preferred for stratification
3. **Number of allowable metastases:**
   ≤ 4 metastases seen on standard imaging within 60 days prior to registration when all metastatic disease is located within the following sites:
   - peripheral lung
   - osseous (bone)
   - spine
   - central lung
   - abdominal–pelvic(lymph node/adrenal gland)
   - liver
   - mediastinal/cervical lymph node
4. All known disease amenable to metastasis-directed therapy with either SBRT or resection;
   NOTE: Symptomatic bone metastasis are allowed if ablative therapy can be delivered.
   NOTE: Sites for possible surgical excision include lung, liver, adrenal gland, bone, small intestine, large intestine, ovary, and amenable nodal disease sites.
   NOTE: Surgical stabilization is allowed for a metastasis if it is followed by conventionally fractionated external beam radiotherapy.
5. Maximum diameter of individual metastasis in any dimension ≤ 5 cm;
6. There are no restrictions on distance between the metastases.
7. Patients must be registered within 365 days of the ***initial*** metastatic breast cancer diagnosis. First-line standard systemic therapy (chemotherapy, anti-endocrine therapy, anti-HER2 or other standard targeted therapy) for metastatic breast cancer must be given or planned to be given. If given before study entry, it cannot have exceeded a duration of 12 months at the time of registration. (Note: Sequencing of ablative therapy (surgery or SBRT) relative to systemic therapy, for patients randomized to Arm 2, is at the discretion of the treating physician.)
   - See Section 5.4.1 for washout required for experimental therapeutics;
8. The primary tumor site must be controlled prior to registration
   - For those who present with s***ynchronous primary*** and oligometastatic disease:
     - Primary must be controlled prior to registration.
     - The definition of control is definitive surgery by excision or mastectomy (+/- radiotherapy) per institution preference
   - For those who present with local recurrence and oligometastatic disease, local recurrence must be controlled prior to registration
     - The definition of control is definitive surgery by excision or mastectomy (+/- radiotherapy) per institution preference
9. Appropriate stage for study entry based on the following diagnostic workup:
   - History/physical examination within 60 days prior to registration;
   - Clinical grade CT scans of the chest, abdomen, and pelvis with radionuclide bone scan OR whole body PET/CT within 60 days prior to study registration;
10. Age ≥ 18

11. Zubrod Performance Status ≤ 2 within 60 days prior to registration;
12. CBC/differential obtained within 60 days prior to registration on study, with adequate bone marrow function defined as follows:
    - Absolute neutrophil count (ANC) ≥ 500 cells/mm^3
    - Platelets ≥ 50,000 cells/mm^3
    - Hemoglobin ≥ 8.0 g/dl (Note: The use of transfusion or other intervention to achieve Hgb ≥ 8.0 g/dl is acceptable)
13. For females of child-bearing potential, negative serum or urine pregnancy test within 14 days prior to study registration;
14. The patient or a legally authorized representative must provide study-specific informed consent prior to study entry.
15. Patient must be female

SCHEMA (14-JUN-2018)



[a] Standard of care systemic therapy for metastatic disease will be given as appropriate for the patient's disease subtype (ER+, HER2 +, TNBC) at the discretion of the treating physician.

[b] Metastatic sites present at registration that require palliation in **Arm 1** can be addressed by standard palliative therapy (i.e., radiotherapy), surgery, or interventions such as vertebroplasty, RFA, etc.) (see Section 5.0).

[c] The selection of either surgery or radiation for ablation of a given metastasis in **Arm 2** is at the discretion of the treating physician. See Sections 5.2 and 5.3.