

Fast Facts

SWOG S0500: A Randomized Phase III Trial to Test the Strategy of Changing Therapy Vs. Maintaining Therapy for Metastatic Breast Cancer Patients who Have Elevated Circulating Tumor Cell Levels at First Follow-Up Assessment

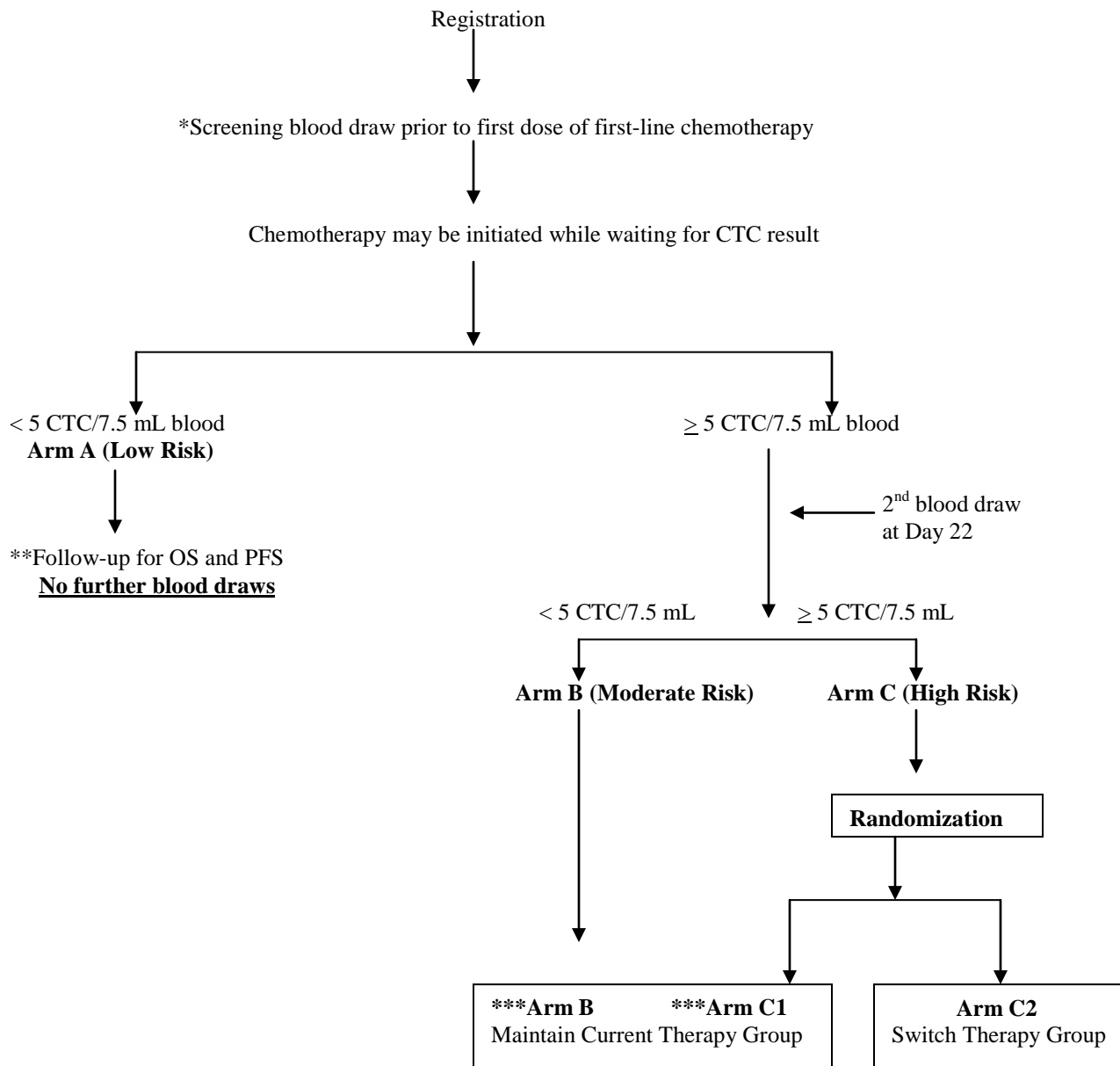
ELIGIBILITY CRITERIA

1. Patients must be women with histologically confirmed breast cancer and clinical evidence of Stage IV disease. (See Section 4.0)
2. Patients must have either 1) measurable disease with or without non-measurable disease, or 2) non-measurable disease only, but the non-measurable disease must include bone metastases. (Note: Patients who only have non-measurable disease without bone involvement are not eligible). All patients must have a CT scan or MRI of the chest and abdomen AND a whole body bone scan or PET scan within 28 days of registration. All other x-rays, scans, or physical examinations used for tumor measurement must have been completed within 28 days prior to registration. X-rays, scans, or other tests for assessment of non-measurable disease must have been performed within 42 days prior to registration.
3. Patients must have HER-2 status determined by IHC and/or FISH assay. HER-2 positivity is defined as any IHC 3+ or FISH+. If the IHC result is indeterminate (2+), FISH must be performed to classify the patient as positive or negative.
4. Patients must be planning to receive chemotherapy. Patients must NOT have received any prior chemotherapy for metastatic disease. Prior use of hormonal therapy, bisphosphonate therapy, trastuzumab and/or bevacizumab in the metastatic setting is acceptable. Patients may have received any number or type of exogenous hormonal therapies, either for metastatic disease and/or as adjuvant therapy.
5. Patients with prior adjuvant chemotherapy must have completed adjuvant chemotherapy at least 12 months prior to registration.
6. Patients must have recovered from any prior surgery. Two weeks are recommended from the time of any minor surgery and four weeks for any major surgery.
7. Patients must agree to the CTC blood draws and submit the initial blood draw **within one day of registration**. Patients must agree to the serum draws to test for the tumor markers, CA 15-4 and CEA, as outlined in Section 15.3. Patients who are willing to have their serum specimens retained for banking must provide additional patient consent as outlined in Section 15.3.
8. The name and contact information of a contact person at the treating institution is required for communication of the CTC results. The name, phone, number, and email address of the contact person must be supplied at the time of patient registration.
9. Patients must have a performance status of 0 – 2 according to Zubrod criteria.
10. Patients with brain metastases must have stable disease for more than 90 days after completing radiotherapy to the brain.
11. Patients must not have leptomeningeal disease.
12. Pregnant or nursing women may not participate in this study due to the potential for congenital abnormalities and the harm to nursing infants when treated with standard of care regimens and because pregnant women are also limited in the types of treatment that they can be given.
13. No prior malignancy is allowed except for adequately treated basal cell or squamous cell skin cancer, any adequately treated Stage I or II cancer from which the patient is currently in complete remission, or any other cancer from which the patient has been disease-free for 5 years.
14. All patients must be informed of the investigational nature of this study and give written informed consent in accordance with institutional and federal guidelines.

PRE-STUDY PARAMETERS

1. H&P; Wt; Performance status
2. HER-2 status
3. These tests are suggested pre-study in accordance with Good Medical Practice: CBC/Diff/Platelets; Hemoglobin; SGOT/SGPT; Alk. Phosphatase; Bilirubin; Serum Creatinine; Pregnancy test (HCG)
4. CT scan (or MRI) of chest/abdomen and bone scan (whole body) – the same method of disease assessment must be used consistently from pre-study throughout follow-up.

TREATMENT PLAN



- * Patients must be registered prior to initiation of testing (no more than one working day prior to initial CTC submission)
- ** Patients in the Low Risk Group (Arm A) may enroll in other clinical trials while being followed for OS and PFS on S0500
- *** Patients in Arms B and C1 and their physicians will be blinded to which arm they are in by study design. Protocol requirements are the same for these two arms.