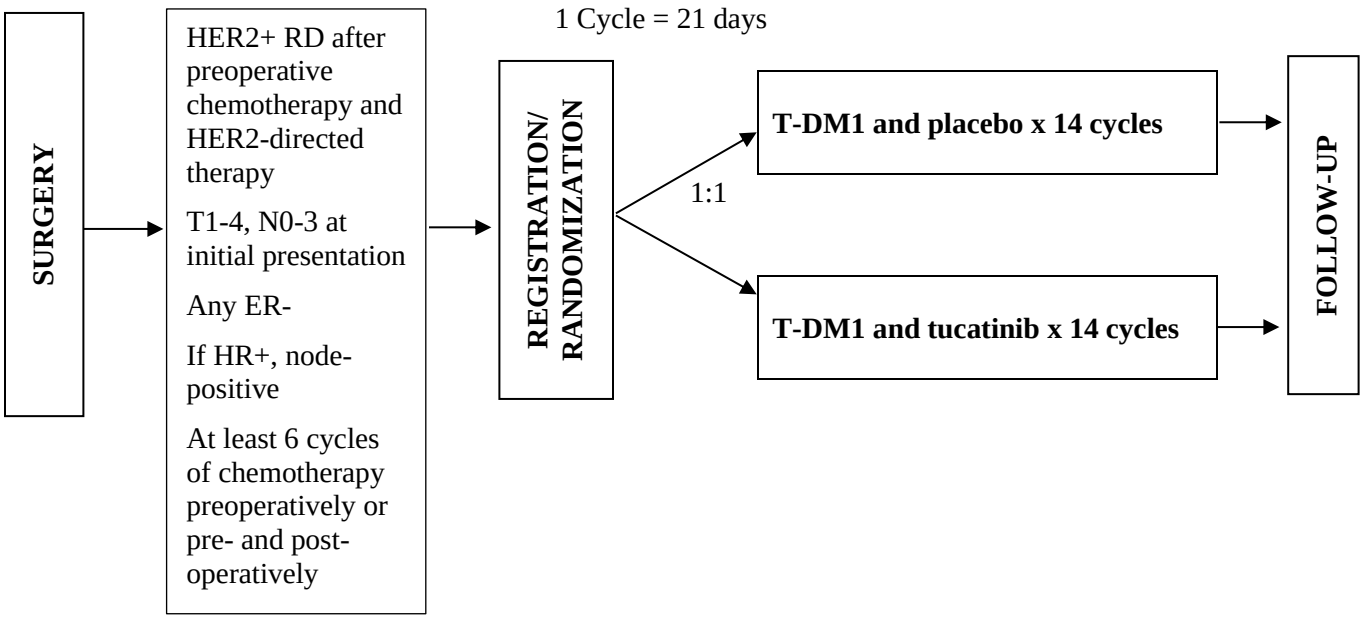
- No history of exposure to the following cumulative doses of anthracyclines: Doxorubicin > 240 mg/m2; Epirubicin or Liposomal Doxorubicin-Hydrochloride (Myocet®) > 480 mg/m2. For other anthracyclines, exposure equivalent to doxorubicin > 240 mg/m2.
- No cardiopulmonary dysfunction as defined in Section 3.2.8.
- No current severe uncontrolled systemic disease
- No major surgical procedure unrelated to breast cancer or significant traumatic injury within 28 days prior to registration or anticipation of the need for major surgery during the course of study treatment. See Section 3.2.8.
- No history of intolerance, including Grade 3 to 4 infusion reaction or hypersensitivity to trastuzumab or murine proteins or any components of the product
- No peripheral neuropathy of any etiology that exceeds grade 1 (mild symptoms)
- No assessment by the investigator as being unable or unwilling to comply with the requirements of the protocol.
- See Section 3.2.9 for concomitant medication restrictions.
- Screening left ventricular ejection fraction (LVEF) ≥ 50% on echocardiogram (ECHO) or multiple-gated acquisition (MUGA) after receiving neoadjuvant chemotherapy and no decrease in LVEF by more than 15 absolute percentage points from the pre-chemotherapy LVEF. Or, if pre-chemotherapy LVEF was not assessed, the screening LVEF must be ≥ 55% after completion of neoadjuvant chemotherapy. Note: LVEF assessment may be repeated once up to 3 weeks following the initial screening assessment to assess eligibility.

Schema



Note: HR stands for "hormone-receptor." Patients with weakly ER-positive (1-10%) and node-negative disease per the surgical pathology report are eligible.

Treatment is to continue until breast cancer recurrence, completion of 14 cycles, or unacceptable adverse event. Patients will be followed for 10 years after registration or until death, whichever comes first.

Please refer to the full protocol text for a complete description of the eligibility criteria and treatment plan.

Chemotherapy will be conducted at the registering institution. Radiation and surgery may be conducted at a non-registering institution. The non-registering institution does not need to be an NCTN site.

If the Group credited for enrollment is a non-Alliance Group, then other requirements from the credited Group may apply.