

FAST FACTS

URCC 16070: TREATMENT OF REFRACTORY NAUSEA

Eligibility Criteria

Cycle 1 portion of the study

1. Have a diagnosis of breast cancer and be chemotherapy naïve. Note: Prior methotrexate for non-cancerous conditions is allowed.
2. Be scheduled to receive a single-day chemotherapy regimen that contains doxorubicin and/or cyclophosphamide and/or carboplatin. Herceptin® (trastuzumab) and other chemotherapy agents will be allowed with any of these regimens.
3. Be scheduled to receive an antiemetic regimen that does not contain Akynzeo®.
 - For chemotherapy regimens with a high emetic risk, the antiemetic regimen must include an NK-1 antagonist receptor, a 5HT3 receptor antagonist and dexamethasone. Other antiemetics, including additional dexamethasone and olanzapine, may also be included at cycle one.
 - For chemotherapy regimens with a moderate emetic risk, the antiemetic regimen must include a 5HT3 receptor antagonist and dexamethasone. Other antiemetics, including additional dexamethasone and olanzapine, may also be included at cycle one.
4. Be able to read English. Materials will not be provided in Spanish because validated translations of most of the study measures are not available in Spanish, and Spanish translating capacity is not available at all affiliate sites.
5. Be at least 18 years of age.
6. Be female.
7. Have the ability to give written informed consent.
8. Have ECOG performance status of 0, 1, or 2
9. Note: Because the NCCN antiemetic guidelines(11) state that olanzapine should be used with caution in elderly patients, patients 80 years of age or older must have approval from an oncologist or their designee to participate in this study.
10. Note: Because aprepitant can lower International Normalized Ratio (INR) levels if taken concurrently with warfarin, patients currently receiving warfarin must have approval from an oncologist or their designee to participate in this study.
11. Women of child-bearing potential must agree to use adequate contraception (hormonal or barrier method of birth control, or abstinence) for the duration of the study and have a negative pregnancy test within 10 days prior to the initiation of chemotherapy. Should a woman become pregnant or suspect she is pregnant while participating in this study, she should inform her study physician immediately.

Cycle 2 portion of the study

1. Only participants with a nausea score > 3 at least once on the 4-day home record from Cycle 1 can be randomized for Cycle 2.
2. Participants must be scheduled to receive the same chemotherapy regimen as received at Cycle 1.
3. Because quinolone antibiotic therapy can increase the level or effect of olanzapine by altering drug metabolism and thereby potentially increase risk of side effects, patients currently receiving quinolone

antibiotic therapy must have approval from an oncologist or their designee to participate in the Cycle 2 portion of the study. (A partial list of quinolone antibiotics is included in the supporting documents section of the protocol webpage.)

Exclusion criteria

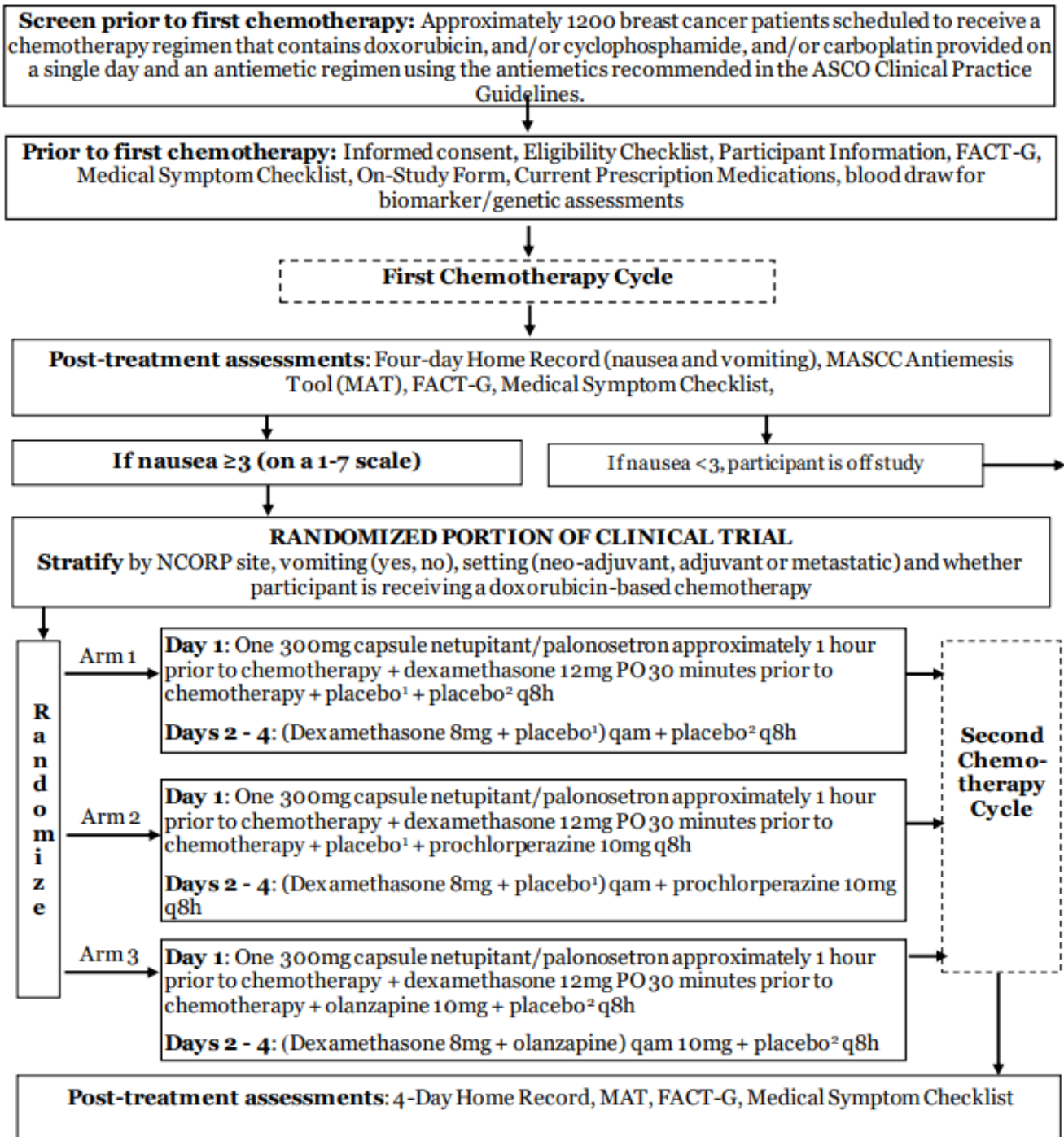
Cycle 1 portion of the study

1. Have clinical evidence of current or impending bowel obstruction.
2. Have a known history of central nervous system disease (e.g., brain metastases or a seizure disorder.)
3. Have dementia.
4. Have uncontrolled diabetes mellitus or uncontrolled hyperglycemia.
5. Have severe hepatic impairment, severe renal impairment, or end-stage renal disease as determined by the treating physician.
6. Have had long-term treatment (> 5 days within the past 30 days) with an antipsychotic agent such as risperidone, quetiapine, clozapine, a phenothiazine, or a butyrophenone within 30 days before enrollment or plans for such treatment during the study period. Note: Participants could have received prochlorperazine and other phenothiazines as antiemetic therapy on a short term basis (i.e., < 5 days). (A partial list of antipsychotic agents is included in the supporting documents section of the protocol webpage.)
7. Have a known cardiac arrhythmia, uncontrolled congestive heart failure, or acute myocardial infarction within the previous 6 months.
8. Be taking benzodiazepines regularly (> 5 days within the past 30 days). PRN use (\leq 5 days) for the short-term relief of the symptoms of anxiety, anxiety associated with depressive symptoms, or as a rescue medication for breakthrough CINV is allowed. (A partial list of benzodiazepines is included in the supporting documents section of the protocol webpage.)
9. Be taking anticholinergic medications. (A partial list of anticholinergic medications is included in the supporting documents section of the protocol webpage.)
10. Be taking amifostine (Ethiofos).
11. Have a known hypersensitivity to olanzapine or to phenothiazines.

Cycle 2 portion of the study

1. Must not have received Akynzeo® at Cycle 1.
2. Must still meet all the exclusion criteria for Cycle 1.

SCHEMA



Note: Placebo¹ matches olanzapine and placebo² matches prochlorperazine.