Cancer Research Consortium of West Michigan
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FAST FACTS

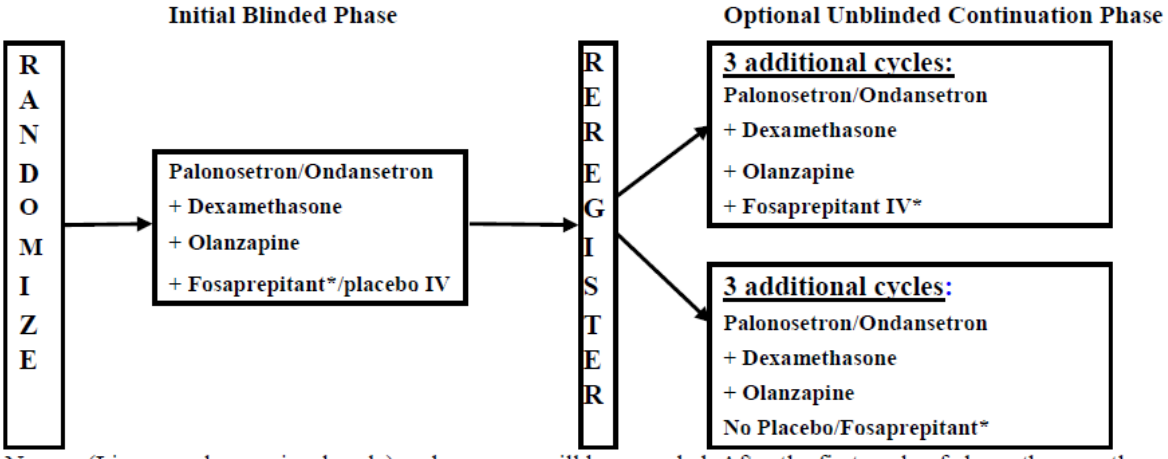
ALLIANCE A221602 - OLANZAPINEWITH ORWITHOUT FOSAPREPITANT FOR THE PREVENTION OF CHEMOTHERAPY INDUCED NAUSEA AND VOMITING (CINV) IN PATIENTS RECEIVING HIGHLY EMETOGENIC CHEMOTHERAPY (HEC): A PHASE III RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL

Eligibility Criteria

1. Diagnosis of malignant disease of any stage. (Stage I through Stage IV)
2. No prior history of systemic chemotherapy for any malignancy.
3. Scheduled to receive intravenous HEC (Highly Emetogenic Chemotherapy) (either cisplatin-containing regimen or doxorubicin and cyclophosphamide [AC]).
   Cisplatin, given on a single day, at a dose of ≥ 70 mg/m2, with or without other chemotherapy agent(s)
   OR
   Doxorubicin (60 mg/m2) plus cyclophosphamide (600 mg/m2)
4. No nausea or vomiting ≤ 24 hours prior to registration.
5. Negative pregnancy test (serum or urine) done ≤ 7 days prior to registration, for women of childbearing potential only.
   A female of childbearing potential is a sexually mature female who: 1) has not undergone a hysterectomy or bilateral oophorectomy; or 2) has not been naturallypostmenopausal for at least 12 consecutive months (i.e., has had menses at any time in the preceding 12 consecutive months).
6. No known diagnosis of dementia. Patients with stable treated brain metastases are eligible to participate.
7. No known history of CNS disease (e.g. seizure disorder).
8. No treatment with another antipsychotic agent such as olanzapine, risperidone, quetiapine, clozapine, phenothiazine or butyrophenone ≤ 30 days prior to registration.
9. No chronic phenothiazine administration as an antipsychotic agent (patients may receive prochloperazine and other phenothiazines as rescue anti-emetic therapy but not within 24 hours prior to registration).
10. No use of amifostine within 7 days prior to registration.
11. No radiotherapy within 7 days prior to registration or planned for one week after the current dose of chemotherapy.
12. No use of quinolone antibiotic therapy within 7 days prior to registration.
13. No chronic alcoholism (as determined by the investigator).
14. No known hypersensitivity to olanzapine.
15. No known uncontrolled cardiac arrhythmia, no known uncontrolled congestive heart failure, or no acute myocardial infarction within the previous six months.
16. No history of uncontrolled diabetes mellitus, i.e., no diabetic ketoacidosis; within 6 months prior to registration. Patients are eligible if they have controlled diabetes on diet, oral agents, and/or insulin.
17. Age ≥18 years.
18. ECOG Performance Status 0, 1 or 2
19. Patients must be able to read and comprehend English. Local translation, including verbal translation of PROs is not permitted.
20. Required Initial Laboratory Values ≤120 days prior to registration

Serum Creatinine	≤ 2.0 mg/dL
AST or ALT	≤ 3 x upper limit of normal (ULN)

Schema



Nausea (Linear analogue visual scale) and response will be recorded. After the first cycle of chemotherapy, the patient will be given the option to continue on the same antiemetic regimen for a maximum of three additional cycles. If the patient agrees, he/she will be unblinded (See Section 8.2.2), re-registered (see Section 4.7.1), and allowed to continue for three additional cycles and evaluated for efficacy and any adverse events.

* Aprepitant IV may be used in place of Fosaprepitant IV for sites that have adopted use of Aprepitant.

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