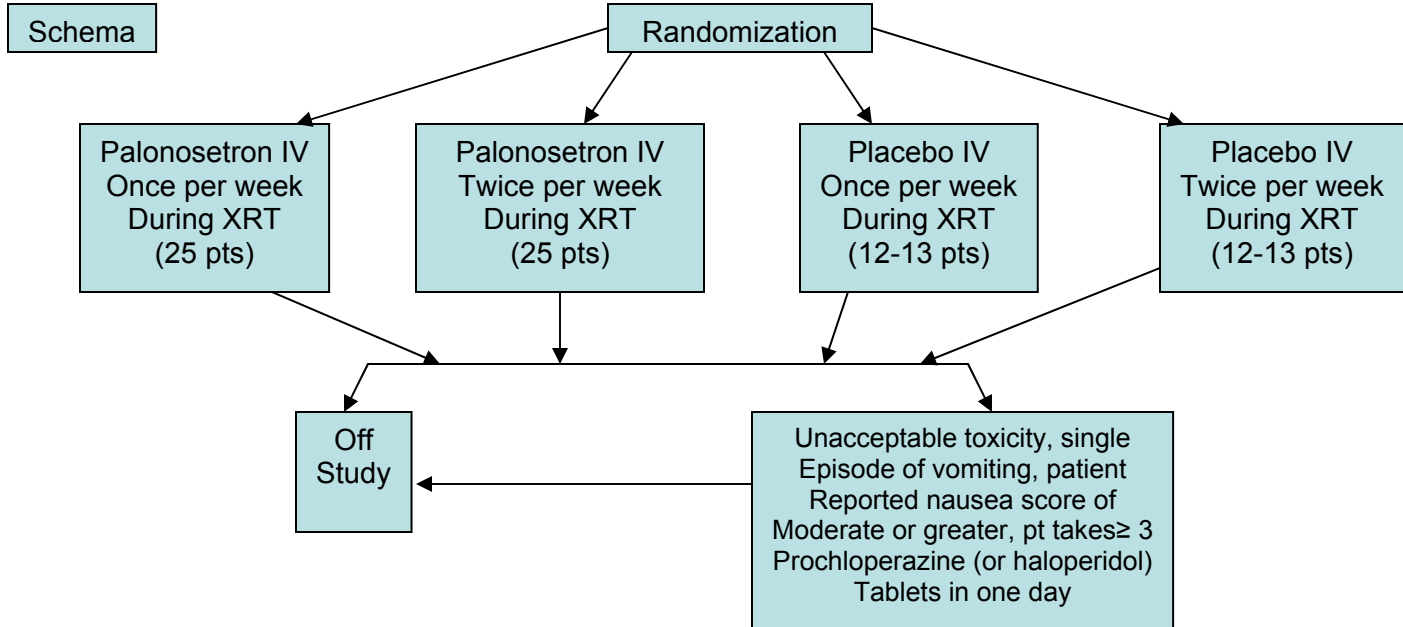


N08C2- A Pilot Phase II, Randomized, Double Blind Trial of Palonosetron versus Placebo to Prevent Radiation Therapy Induced Nausea and Vomiting

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This study is a randomized Phase II, double blind trial looking at the use of Palonosetron versus placebo for the prevention of radiation induced nausea and vomiting. Patients will be randomized in at 2:1 fashion.

Major Inclusion Criteria:

- Scheduled to receive ≥ 3000 cGy or ≥ 3 weeks of external beam radiation to the abdomen for gastrointestinal primaries and/or retroperitoneal sarcomas.
- Radiation therapy fields to extend between T11 and L3, and of a size ≥ 100 cm².
- ECOG PS of 0, 1, or 2.
- Ability to take oral medication (for purposes of rescue medication).

Major Exclusion Criteria:

- Pregnant or nursing women.
- Taking other agents known to have significant effect on emesis¹.
- Receiving chemotherapy¹.
- Receiving cetuximab ≤ 7 days prior to randomization.
- Hypersensitivity to palonosetron or other 5-HT₃ receptor antagonists.
- Presence of brain metastases.
- Receiving oral steroids ≤ 7 days prior to randomization, or planned use during XRT.
- Prior use of palonosetron.
- Presence of any nausea ≤ 48 hours of study enrollment.
- History of dystonic reactions to prochlorperazine, haloperidol, or related agents.

¹ See protocol for more specific details.

Other Key Points:

- Schedule will depend on the day of the week the palonosetron/radiation therapy is started.
- Patients will be given prescription for prochlorperazine or haloperidol to be used as rescue medication. Patients who require ≥ 3 doses in a 24 hour period will go off study.
- Other 5-HT₃ medications are not allowed while patient is on study.

