

NORTH CENTRAL CANCER TREATMENT GROUP

Eligibility Checklist

9/30/2009

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

**To register a patient, fax a completed eligibility checklist to the Registration Office (507/284-0885) between 8 a.m. and 4:30 p.m. Central time Monday through Friday.**

Registration date (date on) (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

Patient study ID number (provided at time of Reg/Random) \_\_\_\_\_

NCCTG member (participant sponsor) \_\_\_\_\_

NCCTG treating location \_\_\_\_\_

NCCTG treating physician \_\_\_\_\_

Institution patient number (local subject number) \_\_\_\_\_

IRB approval date (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

Person Completing Form:

Last Name: **(print)** \_\_\_\_\_ First Name: **(print)** \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_ Email: \_\_\_\_\_

Patient initials (last, first, middle) \_\_\_\_\_

Gender (check one) \_\_\_ Male \_\_\_ Female \_\_\_ Unknown

Date of birth (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

ZIP code \_\_\_\_\_

Country of Residence \_\_\_\_\_

Race (check all that apply)

- White
- Black or African American
- Native Hawaiian or Other Pacific Islander
- Asian
- American Indian or Alaska Native
- Not reported: Patient refused or not available
- Unknown: Patient unsure

Method of payment (check one)

- PI (Private Insurance)
- MR (Medicare)
- MRP (Medicare and Private Insurance)
- MD (Medicaid)
- MM (Medicaid and Medicare)
- MVA (Military or Veterans Sponsored,  
Not Otherwise Specified ( NOS))
- MS (Military Sponsored [including CHAMPUS & TRCARE])
- MV (Veterans Sponsored)
- SP (Self pay [no insurance])
- NP (No means of payment [no insurance])
- OTH (Other)
- UNK (Unknown)

Ethnicity (check one)

- Not Hispanic or Latino
- Hispanic or Latino
- Not reported: Refused or data not available
- Unknown: Unsure of their ethnicity

Patient study ID number \_\_\_\_\_

Eligibility Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be *mm/dd/yyyy*.

**Inclusion Criteria**

Yes No NA

≥18 years of age. Age = _____.	___	___	___
Negative pregnancy test done ≤7 days prior to registration, for women of childbearing potential only. If not a woman of childbearing potential or male ( <i>check NA</i> ) If a woman of childbearing potential – Negative pregnancy test date ___/___/_____	___	___	___
Ability to complete questionnaire(s) by themselves or with assistance.	___	___	___
Willingness to provide informed written consent.	___	___	___
Willingness to return to NCCTG enrolling institution for follow-up.	___	___	___
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 cm <sup>2</sup> .	___	___	___
ECOG Performance Status (PS) of 0, 1, or 2. PS = _____.	___	___	___
Ability to reliably take oral medication (for purposes of rescue medication).	___	___	___

**All responses in above section must be “Yes” unless specified as “NA.”**

**Exclusion Criteria**

Yes No NA

Any of the following because this study involves an investigational agent whose genotoxic, mutagenic and teratogenic effects on the developing fetus and newborn are unknown: <ul style="list-style-type: none"> <li>• Pregnant women</li> <li>• Nursing women</li> <li>• Women of childbearing potential who are unwilling to employ adequate contraception</li> </ul>	___	___	___
Taking other agents known to have significant effect on emesis, including ondansetron, sedating antihistamines, antipsychotics, cannabinoids, corticosteroids, metoclopramide, narcotic analgesics, and benzodiazepines ≤7 days prior to randomization. If no prior agents known to have significant effect on emesis ( <i>check NA</i> ); If prior agents having significant effect on emesis - Last day of agent ___/___/_____	___	___	___
Receiving chemotherapy other than 5FU or capecitabine chemotherapy used as a radio-sensitizer ≤7 days prior to randomization, commencement of radiation therapy, or during the course of radiation therapy; e.g., administration of 5FU or capecitabine up to 7 days prior to the commencement of radiation therapy or administration concurrently with radiation therapy is allowed. If no prior chemotherapy ( <i>check NA</i> ); If prior chemotherapy - Last day of chemotherapy ___/___/_____	___	___	___
Currently receiving cetuximab ≤7 days prior to randomization. If no prior cetuximab ( <i>check NA</i> ); If prior cetuximab - Last day of cetuximab ___/___/_____	___	___	___
Hypersensitivity to palonosetron, or other selective 5-HT <sub>3</sub> receptor antagonists.	___	___	___
Brain metastases (due to risk of nausea and vomiting being caused by increased intracranial pressure).	___	___	___
Patients receiving oral steroids ≤7days prior to randomization, or planning to receive oral steroids during the course of planned irradiation. If no prior oral steroids ( <i>check NA</i> ); if prior oral steroids – Last day of oral steroid ___/___/_____	___	___	___
Co-morbid systemic illnesses or other severe concurrent disease which, in the judgment of the investigator, would make the patient inappropriate for entry into this study or interfere significantly with the proper assessment of safety and toxicity of the prescribed regimens.	___	___	___
Prior use of palonosetron.	___	___	___
Presence of any nausea ≤48 hours prior to study enrollment.	___	___	___
History of dystonic reactions to prochlorperazine or haloperidol or related agents.	___	___	___

**All responses in above section must be “No” unless specified as “NA.”**

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Patient study ID number \_\_\_\_\_

Registration Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be mm/dd/yyyy.

Yes No NA

Consent form signed and dated. Date informed consent signed ___/___/_____	___ ___
Authorization for use and disclosure of protected health information ( <i>U.S.A. institutions only</i> ) signed and dated. If not a USA institution ( <i>check NA</i> ) If a USA institution - Date of authorization ___/___/_____	___ ___
Treatment on this protocol must commence at the accruing membership under the supervision of an NCCTG member physician.	___ ___
Treatment cannot begin prior to registration and must begin $\leq 14$ days after randomization and prior to first dose of radiation.	___ ___
Pretreatment tests/procedures (see Section 4.0) must be completed $\leq 14$ days prior to registration. Earliest pretreatment test date ___/___/_____; latest pretreatment test date ___/___/_____.	___ ___
All required baseline symptoms (see Section 10.3) must be documented and graded.	___ ___
Study drug availability checked.	___ ___
An NCCTG approved radiation oncologist has seen the patient and confirms the patient is a suitable candidate for this study.	___ ___
Patient questionnaire booklet availability checked; copies are not acceptable for this submission.	___ ___

**All responses in above section must be “Yes” unless specified as “NA.”**

Stratification Factors

Planned radiation duration:

- <5 weeks
- $\geq 5$  weeks

Gender:

- Male
- Female

Planned concomitant 5FU therapy:

- Yes
- No

Descriptive Factor

Starting dose day of the week:

- Monday
- Tuesday
- Wednesday
- Thursday
- Friday

Assigned Treatment

Contact person (data manager/nurse/pharmacist) name: \_\_\_\_\_

Contact person may not be involved in assessing adverse events or any other outcome measure. (See Section 6.31)

Contact person (data manager/nurse/pharmacist) phone number: \_\_\_\_\_

Palonosetron vs. Placebo

Person registering Signature \_\_\_\_\_ Registration Office specialist initials \_\_\_\_\_

Physician Signature \_\_\_\_\_ Date (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_