

N064A: Phase II Study of Panitumumab, Chemotherapy and External Beam Radiation in Patients with Locally Advanced Pancreatic Cancer

Fast Facts

Provided Drug: Panitumumab

Inclusion Criteria

1. Histologically or cytology confirmed unresectable adenocarcinoma of the pancreas (includes subtotal resection and gross residual disease). Measurable disease is not required (see sections 11.0 and 11.2).
2. Disease that is encompassable within standard RT fields for pancreatic cancer.
3. Adequate oral nutrition.
4. Age ≥ 18 years.
5. The following laboratory values obtained ≤ 14 days prior to registration:
 - a. ANC $\geq 1500/\text{mm}^3$
 - b. Hgb > 9.0 g/dL
 - c. PLT $\geq 100,000/\text{mm}^3$
 - d. Total bilirubin ≤ 3 x upper limit normal (UNL) (Note: Biliary stent placement or surgical bypass should be considered prior to treatment if impending bile duct obstruction by tumor)
 - e. AST ≤ 3 x UNL
 - f. Creatinine ≤ 2.0 x UNL
 - g. Magnesium $>$ LOWER limit of normal
6. Ability and willingness to provide informed consent.
7. Willingness to return to an NCCTG institution for follow-up.
8. ECOG performance status (PS) 0 or 1.
9. Negative serum pregnancy test ≤ 7 days prior to registration, for women of childbearing potential only.

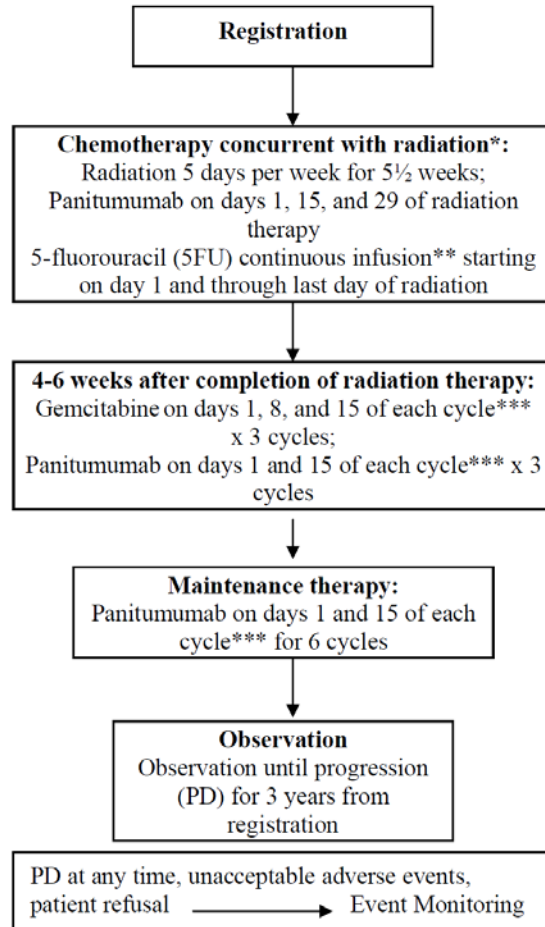
Exclusion Criteria

1. Evidence of metastatic disease outside of the planned radiation therapy field.
2. Distant metastases (i.e., liver or lung metastases or peritoneal spread).
3. Microscopic residual disease only.
4. Laparotomy ≤ 21 days prior to registration.
5. Any of the following:
 - a. Prior anti-EGFR antibody therapy (e.g., cetuximab) or treatment with small molecule EGFR inhibitors (e.g., gefitinib, erlotinib, lapatinib)
 - b. Prior or planned concurrent systemic chemotherapy other than that included in this study or in the context of a clinical trial
 - c. Concurrent or prior malignancy unless disease-free ≥ 3 years except for non-melanoma skin cancer, carcinoma in situ of the cervix, Gleason Grade < 7 organ confined prostate cancer.
 - d. Any previous treatment with radiation therapy that would overlap with planned RT fields
6. Nausea or vomiting $>$ Grade 1.
7. Chronic use of immunosuppressive agents (e.g., methotrexate, cyclosporine, corticosteroids)
8. Any of the following:
 - a. Pregnant women
 - b. Nursing women
 - c. Men or women of childbearing potential who are unwilling to employ adequate contraception during the study and for 6 months after the last treatment with panitumumab. This study involves an investigational agent whose genotoxic, mutagenic, and teratogenic effects on the developing fetus and newborn are unknown.
9. Cystadenocarcinoma of the pancreas or pancreatic tumors of neuroendocrine origin.
10. Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, or psychiatric illness/social situations that would limit compliance with study requirements.
11. History or known presence of central nervous system (CNS) metastases.

12. Clinically significant cardiovascular disease (New York Heart Association >Grade 2), including myocardial infarction, unstable angina, symptomatic congestive heart failure, serious uncontrolled cardiac arrhythmia ≤ 1 year before registration.
13. Known positive test(s) for human immunodeficiency virus infection, hepatitis C virus, acute, or chronic active hepatitis B infection.
14. Enteral hyperalimentation.
15. Current, recent (≤ 4 weeks prior to registration), or planned participation in an experimental drug study other than this study with the exception of studies with specific interventions intended to treat rashes associated with EGFR agents (e.g., N05C4).

Pre-Study Parameters

1. History and physical including height, weight, performance status, AE assessment
2. Labs including CBC, WBC, ANC, Hgb, PLT, total bilirubin, alk. Phos. AST, creatinine, magnesium, pregnancy test for women of child-bearing potential
3. CT or MRI of abdomen/tumor measurement
4. RT consult
5. QOL forms
6. Tissue for central review

Schema:

Note: If a patient is deemed ineligible or a cancel, please refer to Section 13.0 for follow-up information.

* Cycle 1 = days 1-28 of the chemoradiation, cycle 2 starts on day 29 of chemoradiation and goes up until the start of post-RT chemo (gemcitabine + panitumumab).

** Capecitabine may be substituted for 5FU at the discretion of treating physician (see Section 7.21).

*** Cycle length = 28 days for all post-RT chemotherapy including maintenance therapy. Cycle 3 starts on day 1 of the first cycle of post-RT chemo (gemcitabine + panitumumab). Cycle 6 starts on day 1 of the first cycle of maintenance therapy (panitumumab).