Cancer Research Consortium of West Michigan
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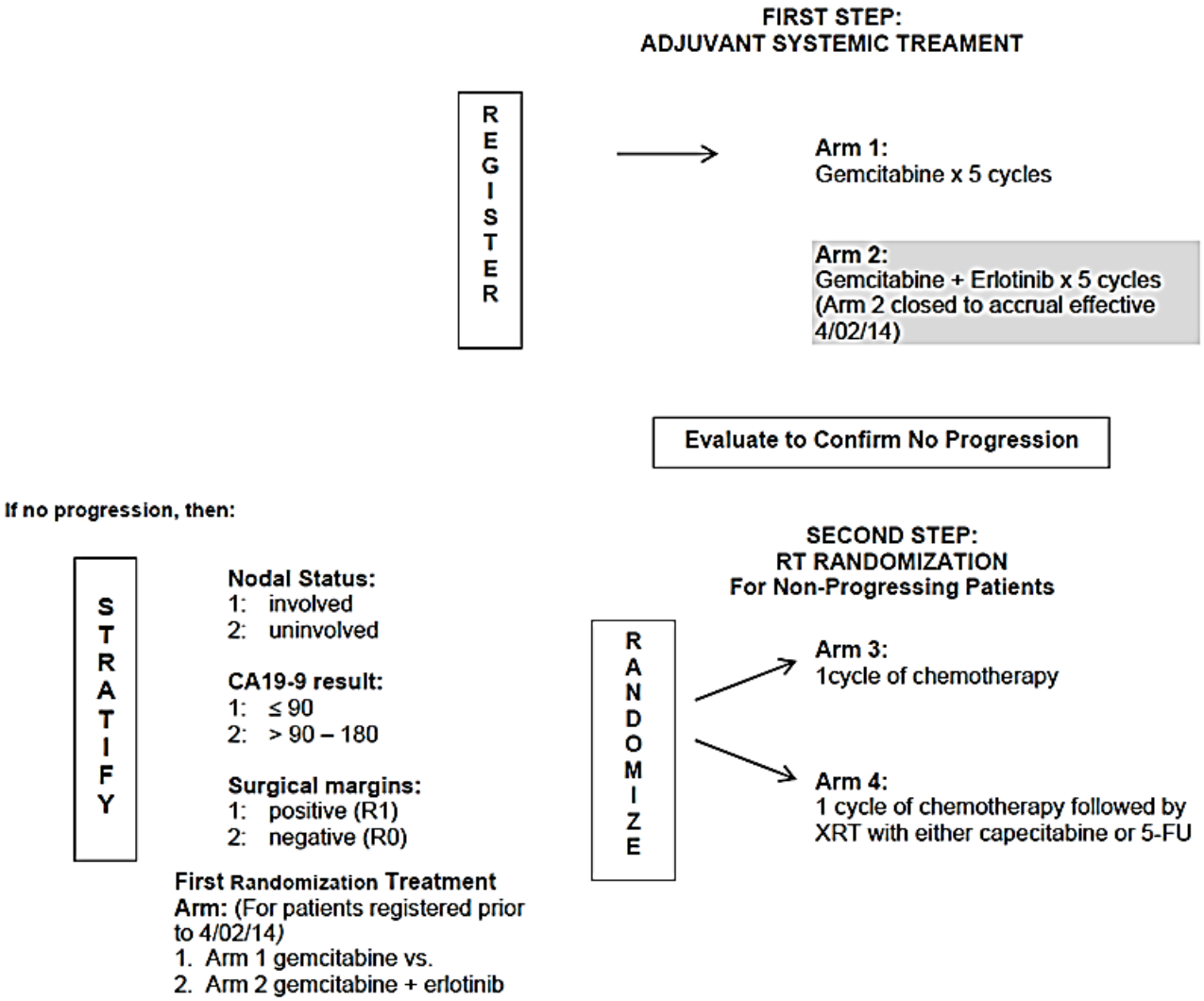
FAST FACTS

RTOG 0848: A Phase II-R and A Phase III Trial Evaluating Both *Erlotinib (Ph II-R) and Chemoradiation (Ph III) as Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma



Conditions for Patient Eligibility

1. Histologic proof of primary head of pancreas invasive adenocarcinoma managed with a potentially curative resection (i.e., removal of all gross tumor) involving a classic pancreaticoduodenectomy (Whipple) or a pylorus preserving pancreaticoduodenectomy. Patients with invasive adenocarcinoma that also contains a component of intraductal papillary mucinous neoplasm (IPMN) are eligible
   The operating surgeon must document in the operative note that a complete gross excision of the primary tumor was achieved. The pathology report must include documentation of the margin status and the size of the tumor. The pathology report must also include the status of the three major margins—bile duct, pancreatic parenchyma, and retroperitoneal (uncinate).
2. For patients who have not started their chemotherapy prior to registration, the interval between definitive tumor-related surgery and 1st step registration must be between 21-70 days. For patients entering on the study who have already received up to 3 months of adjuvant chemotherapy as per the treating institution, the interval between definitive tumor-related surgery and day one of adjuvant chemotherapy must have between 21-77 days.

3. Patients will be staged according to the 6th edition AJCC staging system with pathologic stage T1-3, N0-1, M-0 being eligible. Pathologic reporting using the CAPS format is strongly encouraged (see Appendix IV).
4. Age ≥ 18.
5. Zubrod performance status 0 or 1.
6. Complete history and physical examination including weight and Zubrod status within 31 days of study entry (or within 31 days prior to day 1 of chemotherapy post-surgery for those patients having started chemotherapy prior to first step registration).
7. Before starting therapy the patient should be able to maintain adequate oral nutrition of ≥1500 calories estimated caloric intake per day and be free of significant nausea and vomiting.
8. CBC/differential obtained within 21 days of registration on study (or within 21 days prior to day 1 of chemotherapy post-surgery for those patients having started chemotherapy prior to first step registration), with adequate bone marrow function defined as follows:
   - Absolute neutrophil count (ANC) ≥ 1,500 cells/mm3
   - Platelets ≥ 100,000 cells/mm3
   - Hemoglobin ≥ 8.0 g/dl (Note: The use of transfusion or other intervention to achieve Hgb ≥ 8.0 g/dl is acceptable.)
9. Post resection serum CA19-9 ≤ 180 units/mL AND prior to any systemic treatment.
10. Patients must have:
    - Serum total bilirubin ≤ twice the institutional upper limit of normal within 21 days of registration on study (or within 21 days prior to day 1 of chemotherapy post-surgery for those patients having started chemotherapy prior to first step registration).
    - Creatinine levels ≤ twice the institutional upper limit of normal within 21 days of registration on study (or within 21 days prior to day 1 of chemotherapy post-surgery for those patients having started chemotherapy prior to first step registration).
    - SGOT must be ≤ 2.5 x the institutional upper limit of normal within 21 days of registration on study (or within 21 days prior to day 1 of chemotherapy post-surgery for those patients having started chemotherapy prior to first step registration).
11. Negative serum pregnancy test for women of childbearing potential within 14 days of study registration.
12. Abdominal/pelvic CT scan with contrast is preferred. Abdominal CT alone is acceptable only if insurance restrictions are experienced. Chest CT/x-ray (CT of chest preferred) within 31 days of registration on study (or within 31 days prior to day 1 of chemo post-surgery for those patients having started chemotherapy prior to first step registration). Patients allergic to IV contrast can have MRI of the abdomen/pelvis instead.
13. Signed study-specific informed consent
14. Consultation, agreement, and documentation in the patient's chart by a radiation oncologist that patient is suitable to receive radiotherapy per this protocol.
15. Women of childbearing potential and male participants must practice adequate contraception.
16. Patients with active HIV infection are eligible if their CD4 count is > 499/cu mm and their viral load is < 50 copies/ml; use of HAART is allowed.

Conditions for Patient Ineligibility

1. Patients with non-adenocarcinomas, adenosquamous carcinomas, islet cell (neuroendocrine) tumors, cystadenomas, cystadenocarcinomas, carcinoid tumors, duodenal carcinomas, distal bile duct, and ampullary carcinomas.: Patients with tumors that are largely intraductal papillary mucinous neoplasms (IPMN) with a minimal or minor component of invasive carcinoma are not eligible. Patients with acinar carcinomas are not eligible. Patients with IPMN's that contain some secondary (minor) foci of adenocarcinoma are also not eligible.
2. Patients managed with a total pancreatectomy, a distal pancreatectomy, or central pancreatectomy.
3. Patients entering on the study after pancreaticoduodenctomy, who have not already started chemotherapy must not have had prior systemic chemotherapy for pancreas cancer; note that prior chemotherapy for a different cancer is allowable.

For patients entering on the study who have already received up to 3 months of adjuvant chemotherapy as per the treating institution, patients must not have received adjuvant chemotherapy with agents other than gemcitabine, nab-paclitaxel, oxaliplatin, fluoropyrimidine, or irinotecan for the current pancreatic cancer. Prior chemotherapy for a different cancer is allowable Prior radiotherapy to the region of the study cancer that would result in overlap of radiation therapy fields

4. Prior radiotherapy to the region of the study cancer that would result in overlap of radiation therapy fields
5. Previous history of invasive malignancy (except non-melanoma skin cancer) unless the patient has been disease free for at least 2 years prior to study entry (or first day of chemotherapy for patients having started chemotherapy prior to first step registration). Patients with a previous history of carcinoma *in situ* are eligible.
6. Severe, active co-morbidity, defined as follows per time points indicated below (or per time points indicated below prior to the first day of chemotherapy for patients having started chemotherapy prior to first step registration):
    - Unstable angina and/or congestive heart failure requiring hospitalization within the last 6 months
    - Transmural myocardial infarction within the 3 months of study registration
    - Acute bacterial or fungal infection requiring intravenous antibiotics at the time of registration
    - Chronic Obstructive Pulmonary Disease exacerbation or other respiratory illness requiring hospitalization or precluding study therapy at the time of registration
7. Pregnant or lactating women
8. Women of childbearing potential and men who are sexually active and not willing/able to use medically acceptable forms of contraception; this exclusion is necessary because the treatment involved in this study may be significantly teratogenic.
9. If surgical margin status cannot be determined after consultation with the operating surgeon and the institutional pathologist, the patient will be ineligible.

Required Evaluations/Management

See Appendix I; note that failure to perform one or more of these tests may result in assessment of a protocol violation: Glucose and Na, K, Cl, CO2, BUN within 21 days of study entry or within 21 days prior to day 1 of chemotherapy post-surgery for patients having started chemotherapy prior to first step registration

Highly Recommended Evaluations/Management

1. If patient consents, a tumor tissue block containing normal tissue and peripheral blood that was obtained prior to treatment submitted for correlative studies is highly recommended. (NOTE: Tissue block that includes normal tissue is encouraged).
2. If patient consents, urine specimen prior to protocol therapy.
3. If the patient consents to participate in the quality of life (QOL) component of the study, sites are required to administer the baseline QOL and functional assessments prior to the start of protocol treatment: FACIT-Fatigue and the PROMIS-derived fatigue short form

Pre-Study Parameters

- History & Physical
- CT/MRI of abdomen/pelvis, Chest CT or x-ray
- CBC/diff/platelets, CMP, Post-op CA19-9, Pregnancy test,
- Urine submission, tissue and blood submission