S1505

A Randomized Phase II Study of Peripoerative mFOLFIRINOX versus Gemcitabine/nab-Paclitaxel as Therapy for Resectable Pancreatic Adenocarcinoma

Experimental Arm A (mFOLFIRINOX, surgery)
Patients receive oxaliplatin IV over 2 hours and irinotecan hydrochloride IV over 90 minutes on days 1 and 15. Patients also receive 5-FU IV over 46 hours on days 1-3 and 15-17. Treatment repeats every 28 days for 3 courses in the absence of disease progression or unacceptable toxicity. Patients achieving stable disease or better undergo pancreatectomy 4-8 weeks after completion of first 3 courses of treatment. Within 4-8 weeks following pancreatectomy, patients receive an additional 3 courses of oxaliplatin, irinotecan hydrochloride, and fluorouracil treatment in the absence of disease progression or unacceptable toxicity.

Experimental Arm A (gemcitabine, nab-paclitaxel, and surgery)
Patients receive paclitaxel IV over 30 minutes and gemcitabine IV over 30 minutes on days 1, 8, and 15. Treatment repeats every 28 days for 3 courses in the absence of disease progression or unacceptable toxicity. Patients achieving stable disease or better undergo pancreatectomy 4-8 weeks after completion of first 3 courses of treatment. Within 4-8 weeks following pancreatectomy, patients receive an additional 3 courses of paclitaxel albumin-stabilized nanoparticle formulation and gemcitabine hydrochloride treatment in the absence of disease progression or unacceptable toxicity.

Inclusion Criteria:

- Patients must have histologically or cytologically proven pancreatic adenocarcinoma; histologies other than adenocarcinoma, or any mixed histologies, will NOT be eligible
- Patients must have measurable disease in the pancreas; CT or MRIs used to assess measurable disease must have been completed within 28 days prior to registration; all disease must be assessed and documented on the baseline tumor assessment form
- Patients must have resectable primary tumor based on contrast-enhanced CT or MRI (CT or MRI without contrast as part of PET/CT or PET/MRI is NOT acceptable; CT or MRI with contrast as part of PET/CT or PET/MRI is acceptable), where resectable is defined as:
    - No involvement of the celiac artery, common hepatic artery, and superior mesenteric artery (and, if present, replaced right hepatic artery)
    - No involvement, or < 180° interface between tumor and vessel wall, of the portal vein and/or superior mesenteric vein; and patent portal vein/splenic vein confluence
    - No evidence of metastatic disease
- CT scans or MRIs used to assess disease at baseline must be submitted for central review
- Patients must have surgical consult to verify patient is a surgical candidate within 21 days prior to registration
- Patients must not have received prior surgery, radiation therapy, chemotherapy, targeted therapy, or any investigational therapy for pancreatic cancer
- Patients must have a Zubrod performance status of 0-1; ANC >= 1,500/mcL; Platelets >= 100,000/mcL; Hemoglobin >= 9 g/dL; Total bilirubin =< 1.5 x institutional upper limit of normal (IULN); AST and ALT =< 2.5 x IULN; Serum albumin >= 3 g/dL; Serum creatinine =< IULN within 14 days prior to registration
- Patients with uncontrolled intercurrent illness including, but not limited to ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements will NOT be eligible
- No prior malignancy is allowed except for adequately treated basal (or squamous cell) skin cancer, in situ cervical cancer or other cancer for which the patient has been disease and treatment-free for two years
- Patients must not be pregnant or nursing; women/men of reproductive potential must have agreed to use an effective contraceptive method for up to 3 months after the final administered dose of chemotherapy; a woman is considered to be of "reproductive potential" if she has had menses at any time in the preceding 12 consecutive months; in addition to routine contraceptive methods, "effective contraception" also includes heterosexual celibacy and surgery intended to prevent pregnancy (or with a side-effect of pregnancy prevention) defined as a hysterectomy, bilateral oophorectomy or bilateral tubal ligation; however, if at any point a previously celibate patient chooses to become heterosexually active during the time period for use of contraceptive measures, he/she is responsible for beginning contraceptive measures
- Sites must seek additional patient consent for the future use of specimens
- Patients must be informed of the investigational nature of this study and must sign and give written informed consent in accordance with institutional and federal guidelines