Alliance A021501: Preoperative Extended Chemotherapy vs. Chemotherapy Plus Hypofractionated Radiation Therapy for Borderline Resectable Adenocarcinoma of the Head of the Pancreas

Matthew Katz, MD, FACS

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Background

- Study designed to evaluate the efficacy of two rational neoadjuvant treatment regimens.
- Neoadjuvant chemotherapy alone does not preclude R0 resection of radiographically resectable PDAC, and it is associated with reasonable rates of OS.
- Neoadjuvant chemotherapy is well tolerated and selects patients with borderline resectable PDAC for surgical resection.
- Neoadjuvant gemcitabine-based chemotherapy with standard chemoradiation is associated with favorable outcomes and high R0 resection rates in patients with borderline resectable PDAC but is not associated with a high radiographic response based on RECIST or “downstaging” of the pancreas tumor.
- An initial pilot study showed that FOLFIRINOX-based multimodality therapy for borderline resectable PDAC is well tolerated and study of this approach is feasible in the cooperative group setting.
- Hypofractionated radiation therapy, either alone or preceded by systemic therapy, does not preclude R0 resection of radiographically resectable PDAC, and it is associated with reasonable rates of local control and OS.

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Objective

Primary

- To evaluate and estimate 18 months overall survival (OS) rate of patients with borderline resectable PDAC receiving neoadjuvant therapy consisting of one of the following regimens prior to intended surgical resection and adjuvant therapy with 4 cycles of FOLFOX:
  - Arm 1: 8 cycles of systemic FOLFIRINOX, and/or
  - Arm 2: 7 cycles of systemic FOLFIRINOX followed by hypofractionated radiation therapy

Secondary

- To evaluate and estimate the R0 resection rates in patients receiving each of the two multimodality treatment regimens.
- To evaluate and estimate the event-free survival in patients receiving each of the two multimodality treatment regimens.
- To evaluate and estimate the pathologic compete response (pCR) rates in patients receiving each of the two multimodality treatment regimens
- To assess the adverse events (AE) profile and safety of each treatment arm, using the CTC-AE and PRO-CTCAE.

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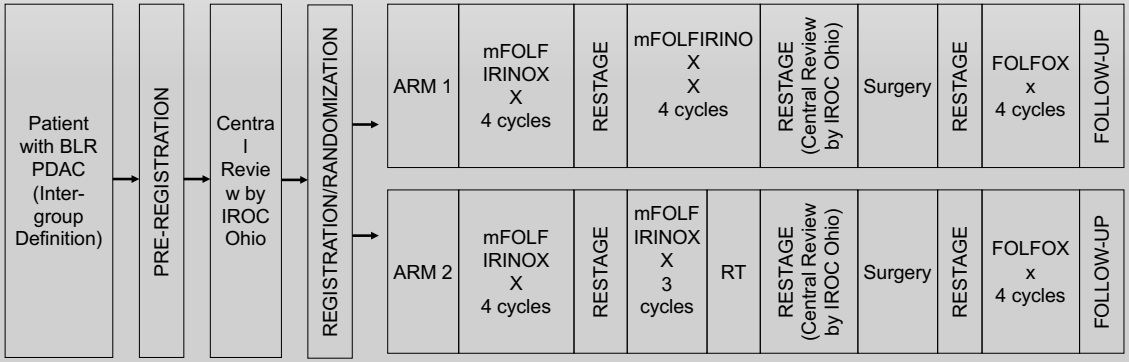
Study Schema



RT simulation and EUS/fiducial marker placement is performed during cycle 5 or 6 of mFOLFIRINOX

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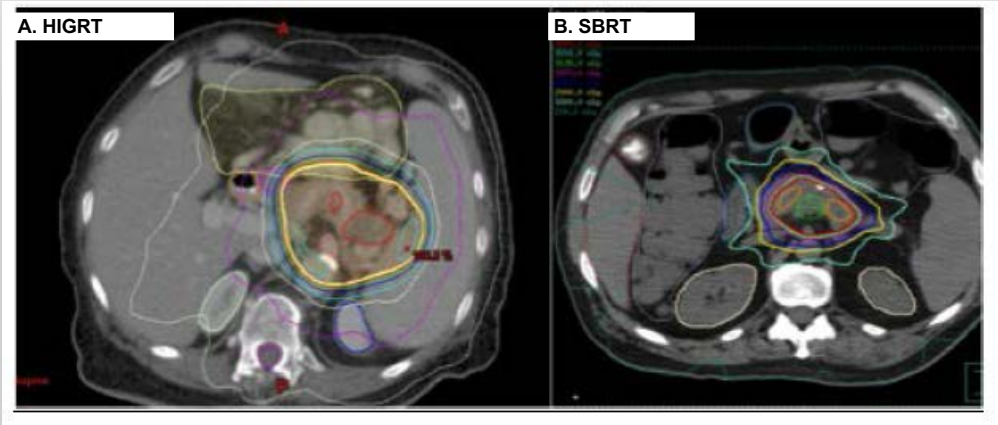
Hypofractionated Radiation Therapy: Modern Techniques



Hypofractionated radiation therapy may be delivered using two similar techniques over an abbreviated 5-day schedule. Both short-course hypofractionated image guided radiation therapy (HIGRT, 5 Gy x 5) and stereotactic body radiation therapy (SBRT, 6.6 Gy x 5) are delivered over 5 consecutive days (see figures to left for comparison).

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Key Eligibility Criteria

Pre-Eligibility

- Cytologic or histologic proof of adenocarcinoma of the pancreatic head or uncinate process. Diagnosis should be verified by local pathologist.
  TNM Stage: TX, T1-4N0-1orNxM0*
  - *M1 disease includes spread to distant lymph nodes, organs, and ascites
- Criteria for borderline resectable disease: Local radiographic reading must be consistent with borderline resectable cancer of the pancreatic head as defined by intergroup radiographic criteria

Eligibility

- Confirmation of radiographic stage as borderline resectable disease by real-time Alliance central radiographic review.
- No prior chemotherapy or radiation for pancreatic CA
- No definitive resection of pancreatic CA
- No concomitant medications that are strong inhibitors or inducers of CYP3A4.
- No grade ≥ 2 neuropathy
- No know Gilbert's Syndrome or known homozygosity for UGAT1A1*28 polymorphism
- No uncontrolled gastric ulcer disease (grade 3) within 28 days of registration.
- No pregnant or nursing women
- CBC, LFT's and creatinine requirements as outlined in protocol

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