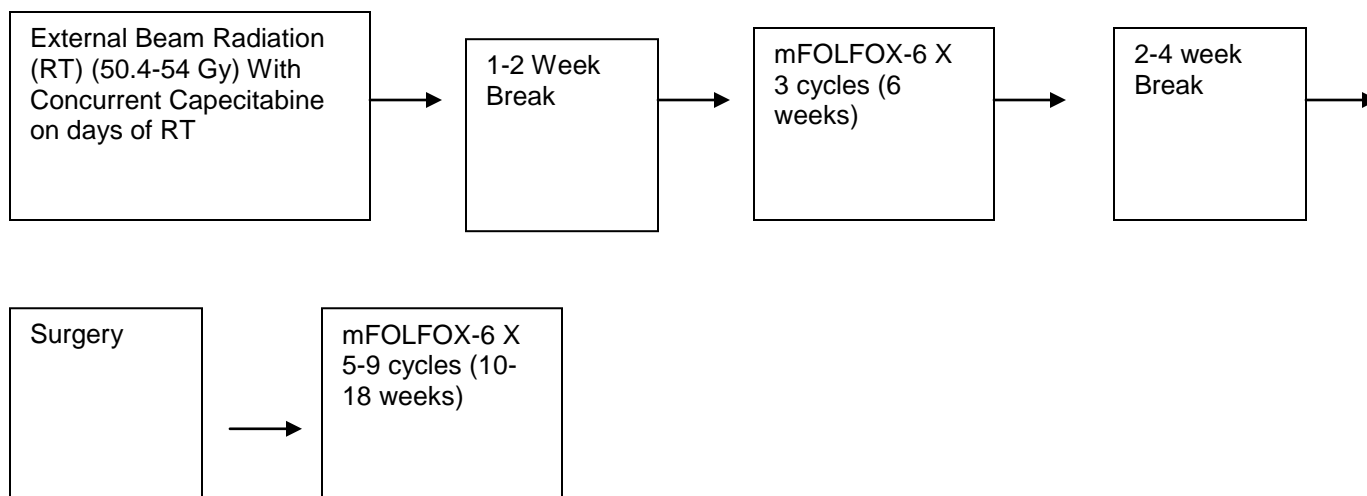


A Pilot and Phase II Study of Altered Chemotherapy Sequencing During Neoadjuvant Therapy for Patients with Stage II or III Rectal Adenocarcinoma

Schema



Objectives

- The primary objective of the pilot portion of this study is to establish the safety and tolerability of an extended treatment break period in patients who have undergone neoadjuvant chemoradiotherapy as well as use of systemic therapy (FOLFOX) during this break.
- The objective of the phase II portion of the study is to determine the histopathologic complete response rate to this altered neoadjuvant therapy strategy.

Patient Selection

Conditions for patient eligibility

- Signed study-specific informed consent form.
- Age ≥ 18
- Zubrod performance status 0-1
- Biopsy proven primary malignancy
- AJCC Stage II or III disease (T3-4 and/or N1-2 disease) as determined by endoscopic ultrasound.
- Pretreatment rectal endoscopic ultrasound, colonoscopy, CT of chest, abdomen, and pelvis, and laboratory values as discussed below.

Conditions for patient ineligibility

- History of inflammatory bowel disease.
- Previous pelvic radiotherapy
- A major psychiatric illness which would limit understanding of the proposed protocol treatment and consent process.
- Men and women of reproductive potential must agree to use an effective contraception method.

- Pregnant or lactating women.
- Severe, active co-morbidity, defined as
 - Unstable angina and/or CHF requiring hospitalization within the last six months.
 - Transmural myocardial infarction within the last 6 months.
 - Acute bacterial or fungal infection requiring intravenous antibiotics at the time of registration.
 - Presence of metastatic disease, including liver metastases
- Laboratory exclusion criteria

Study Flow Chart

Procedures	Pre-Treatment	During Treatment			Post Treatment Follow-up
		Weekly during concurrent therapy	Before each cycle of post-chemoradiation therapy	Before each cycle of post-surgery therapy	
	Within 8 weeks prior to registration				(at Q3 month intervals for first two years, then Q6 months in subsequent years)
Medical History	X				X
Physical Examination, Zubrod	X	X	X	X	X
RT, Surgery, and MedOnc Consults	X				
Vital Signs, height, weight and BSA	X	X	X	X	X
Toxicity assessment / adverse events		X	X	X	X
CBC with differential and platelet count	X	X	X	X	X
Bilirubin, SGOT or SGPT, alk. phos., serum creatinine, and glucose	X	X	X	X	X
PT and PT-INR	X				
CEA	X				X
Pregnancy test (urine or serum)	X				
Endoscopic ultrasound of rectum	X				
CT scan of Chest, abdomen, and pelvis, Colonoscopy	X				X (at discretion of treating oncologists)