PROSPECT (N1048)
For Patients with Locally Advanced Rectal Cancer

PROSPECT Available Through the CTSU
N1048: A Phase II/III Trial of Neoadjuvant FOLFOX with Selective Use of Combined Modality Chemoradiation versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision

Patient Population
See Section 3.0 for Complete Eligibility Details

- Diagnosis of rectal adenocarcinoma
- In the absence of a clinical trial, the standard treatment would be combined modality neoadjuvant chemoradiation followed by curative intent surgical resection
- Candidate for sphincter-sparing surgical resection prior to neoadjuvant therapy
- Clinical stage T2N1, T3N0, T3N1; not T4
- No tumor adhering to or invading the mesorectal fascia on imaging studies, such that the surgeon would be unable to perform R0 resection
- No symptomatic bowel obstruction (patients having had a temporary diverting ostomy are eligible)
- No chemotherapy within 5 years prior to registration (Hormonal therapy is allowable)
- No prior pelvic radiation

- Number of Participants: 1060

Treatment Plan
See Section 7.0 for Complete Treatment Details

Group 1 (FOLFOX):
- Oxaliplatin 85 mg/m² IV Day 1
- Leucovorin 400 mg/m² bolus IV Day 1
- 5FU 400 mg/m² bolus IV Day 1
- 5FU 2400 mg/m² CIVI over 46-48 hours Days 1-2
- Give 6 14-day cycles
If restaging shows limited regression OR progressive disease after 6 cycles of FOLFOX, patient should receive 5FUCMT (see regimen below) prior to proceeding to surgery. Postoperative 5FUCMT is allowed if adverse pathologic features noted in TME (e.g., T4 or positive margin).

Group 2 (5FUCMT):
- 5FU 225 mg/m²/day CIVI either 5 or 7 days/week for duration of RT -or-
- Capecitabine 825 mg/m² PO BID 5 days/week on days of planned RT.
- Radiation 1.8 Gy/day 5 days a week for 25 initial fractions and 3 boost fractions (50.4 Gy total)

Groups 1 and 2:
- Proceed to low anterior resection with total mesenteric excision.
- Follow with suggested adjuvant chemotherapy as described in protocol.

Patient Enrollment
All Sites: Oncology Patient Enrollment Network (OPEN) https://open.ctsu.org

Protocol Information
CTSU Help Desk: 1-888-823-5923, CTSUcontact@westat.com, www.ctsu.org
Please contact Protocol Chair Deb Schrag at deb_schrag@dfci.harvard.edu or Protocol Coordinator Vance N. Erese at verese@uchicago.edu with questions.

Please Enroll Your Eligible Patients!
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