Trial of the Efficacy and Safety of Short and Long Course Radiation Therapy With/Without BMX-001

NCT05254327

Status	RECRUITING
Phase	Phase 2
Sponsor	University of Nebraska
Enrollment	118 participants

Plain Language Summary

This study is testing whether adding a drug called BMX-001 to standard radiation therapy improves treatment for patients with locally advanced rectal cancer receiving total neoadjuvant therapy (chemotherapy and radiation before surgery). BMX-001 is a drug that may protect healthy tissue from radiation damage while potentially making cancer cells more vulnerable.

You may be eligible if...
- You are 18 or older (19 or older in Nebraska)
- You have confirmed stage II or III rectal adenocarcinoma (rectal cancer, not yet spread to other organs)
- You are scheduled for total neoadjuvant therapy (chemotherapy and radiation before surgery) with curative intent
- Your blood counts and organ function meet required levels
- You are in reasonably good physical condition (ECOG 0-2)

You may NOT be eligible if...
- Your cancer has already spread to other organs
- You have severe blood, liver, or kidney problems
- You are pregnant or planning to become pregnant during the study period
- You have had prior pelvic radiation

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (8)

- Patients with pathologically confirmed locally advanced rectal adenocarcinoma who will be receiving total neoadjuvant therapy regimen with curative intent.
- AJCC stage II to III rectal adenocarcinoma that will require total neoadjuvant therapy.
- Adult, age \> or equal to 18 years (for Nebraska, age of consent is e19 years old)
- ECOG Performance Status 0-2
- Hemoglobin e 9.0 g/dl, ANC e 1,500 /dl, platelets e 100,000 /dl (The use of transfusion or other intervention to achieve Hgb \> 9.0 g/dl is acceptable)

... and 3 more (see full listing online)

Exclusion (16)

- Breast-feeding or pregnant
- Active infection requiring IV antibiotics 7 days before enrollment
- Prior, unrelated malignancy requiring current active treatment with the exception of cervical carcinoma in situ, basal cell or carcinoma of the skin, invasive cancers with a 5-year disease-free interval, resected cancer of the bladder or low-grade (Gleason 6 or less) prostate cancer
- Prior history of rectal adenocarcinoma (RAC)

• Prior history of pelvic radiotherapy for any other type of malignancy

... and 11 more (see full listing online)

Locations (3 total)

UT Health San Antonio MD Anderson Cancer Center, San Antonio, Texas, United States
University of Nebraska Medical Center, Omaha, Nebraska, United States
Markey Cancer Center, Lexington, Kentucky, United States