

# SurgeryNews

## RESEARCH Aims to Improve Survival for RECTAL CANCER Patients

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Two unique cancer trials getting underway at Beth Israel Medical Center have the potential to help change the way rectal cancer is treated. The first, a major international Phase III trial, is investigating a preoperative radiation-only protocol for lower rectal adenocarcinoma. The second, a Phase II trial for mid- and upper-rectum disease, looks at a neoadjuvant, chemotherapy-only approach.

Beth Israel is one of a few U.S. sites for these studies, conducted under the auspices of the multi-disciplinary GI Institute, affiliated with the Continuum Cancer Centers of New York.

For years, the focus for treating rectal cancer has been on cure and prevention of local recurrence. With total mesorectal excision (TME), the worldwide gold standard technique that Warren E. Enker, MD, and his colleagues developed, and adjuvant chemoradiotherapy, surgeons have become adept at removing the tumor and preventing recurrence, while preserving sphincter, sexual and urinary functions. TME alone has dramatically improved survival compared with prior conventional surgery, but neoadjuvant chemoradiation therapy has reaped less

success. Metastases occur most often in the lung and liver. **Now researchers are refocusing to reduce treatment toxicities, preserve function and hopefully boost survival.**

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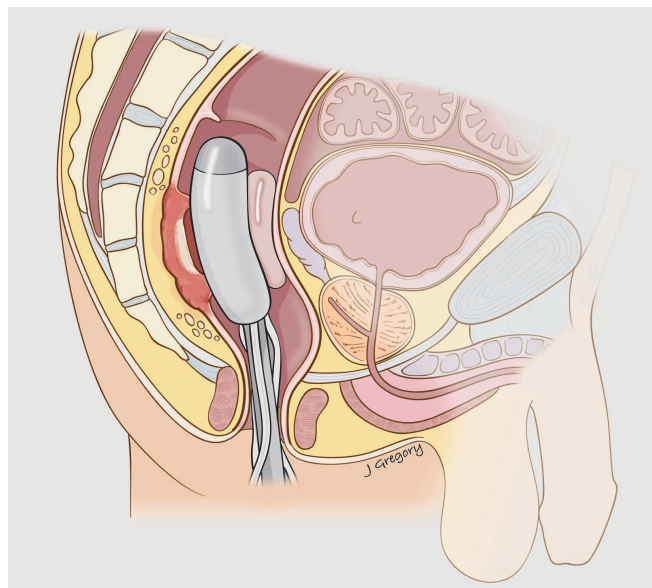
The radiation-only protocol involves high-dose-rate endorectal brachytherapy (HDR-ERBT), a technique delivering radioactive isotopes through the rectum to a location adjacent to the tumor. Under the guidance of principal investigator Kenneth Hu, MD, a radiation oncologist, four daily high-dose treatments are administered in the lower six centimeters of the rectum via a balloon applicator, followed by an eight-week wait before surgery. Brachytherapy, the only approach known to increase sphincter preservation, avoids long-term toxicities often associated with external beam radiation.

The second trial, headed by hematologist/oncologist Peter Kozuch, MD, entitled COMURC (Chemotherapy Only for Mid-to Upper-Rectal Cancer), is for patients with malignancies in the upper

6 to 12 centimeters, where there are generally fewer lymph node metastases and higher cure rates than distal cancer. The question is whether chemotherapy alone can impact survival, given that even with TME, metastases occur two to seven times more often than local recurrences. Eight weeks of chemotherapy will be followed by six weeks of rest before surgery.

**Suitable candidates for both research studies will have T3N0 or T3N1 cancer, diagnosed by endoscopic ultrasound (EUS) and confirmed by high definition MRI.**

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During rectal cancer treatment with high-dose-rate endorectal brachytherapy (HDR-ERBT), the balloon applicator is positioned immediately adjacent to the tumor.

## RECTAL CANCER RESEARCH

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Patients are then directed to either the HDR-ERBT trial or the COMURC trial, depending on the tumor's location.

**Patients with early stage T1 or T2 tumors, for whom simple surgery offers a cure, will be ruled out,** as are those with T4 or N2 lesions or metastases, who should have external irradiation. Patients with prior pelvic irradiation will be excluded as well.

All subjects will have pathology tests done at surgery and tumor regression grades (TRG) assigned by a standardized scoring system, ranging from zero for no tumor regression to four for complete regression.



**For further information or to refer a patient for trial consideration, please contact Warren Enker, MD, Division of Colorectal Surgery at (212) 420-3960, or Kenneth Hu, MD, at (212) 844-2022, or Peter Kozuch, MD, at (212) 844-8070.**