

Clinical Trial in the Spotlight

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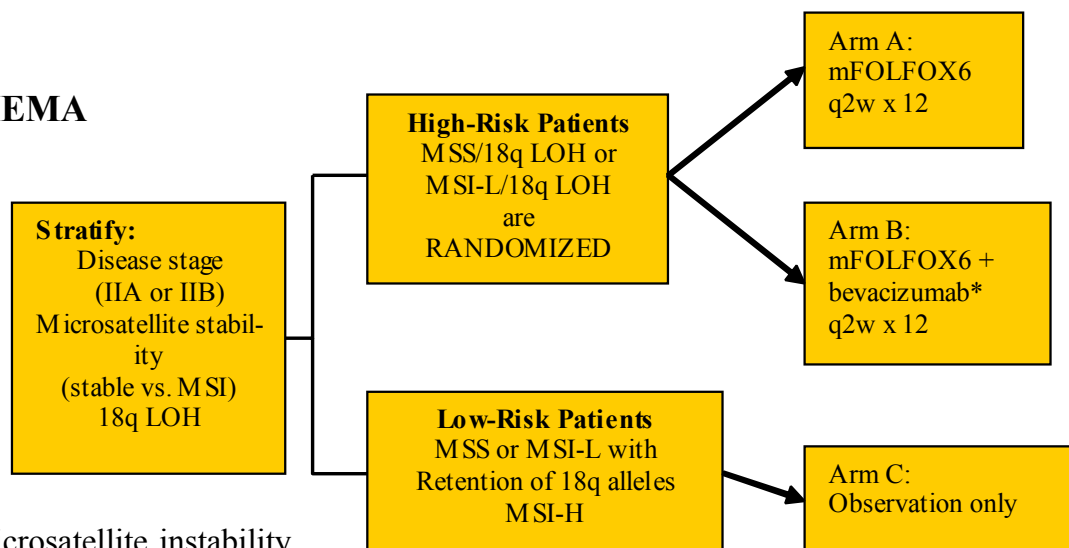
A Randomized Phase III Study Comparing 5-FU Leucovorin and Oxaliplatin versus 5-FU, Leucovorin, Oxaliplatin and Bevacizumab in Patients with Stage II Colon Cancer at High Risk for Recurrence to Determine Prospectively the Prognostic Value of Molecular Markers

This is a randomized study in which patients are stratified according to disease stage (IIA vs. IIB) and microsatellite stability (MSS) (stable vs. low-grade instability [MSI-L]) into one of three arms. (Please see schema for more information) Patients with disease that is at high risk for microsatellite instability (MSI) and loss of heterozygosity (LOH) at chromosome 18q are randomized to either arm I or arm II. Patients with disease that is at low risk for MSI and 18q LOH are assigned to arm III.

Eligibility criteria for this trial includes, but is not limited to:

- Histologically confirmed adenocarcinoma of the colon that is Stage II (T3,4 N0 M0).
- Distal extent of tumor must be > 12cm from the anal verge as determined via endoscopy or surgery.
- Patients must have e² 8 lymph nodes evaluated and reported.
- Patients must have paraffin-embedded tumor specimen (and normal mucosa) available for central evaluation and risk assessment.
- Patients must not have isolated, distant, or non contiguous intra-abdominal metastases even if restricted.
- Patients must not have presented with complete obstruction or perforation of the bowel.
- Patients must not have synchronous tumors, appendiceal tumors, or history of IBD.
- Patients may not have had any systemic or radiation therapy for this malignancy.
- Patients must be > 18 yrs old; ECOG PS 0-2.
- There must be postoperative evidence of adequate hepatic and renal function.
- Patients should not have any concurrent systemic disease that would preclude participation in the study.

TRIAL SCHEMA



MSI-L = low-level microsatellite instability
MSI-H = high-level microsatellite instability
*bevacizumab continued for an additional 6 months