

Fast Facts

WF 1806 - Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer: The M&M Study

Eligibility criteria

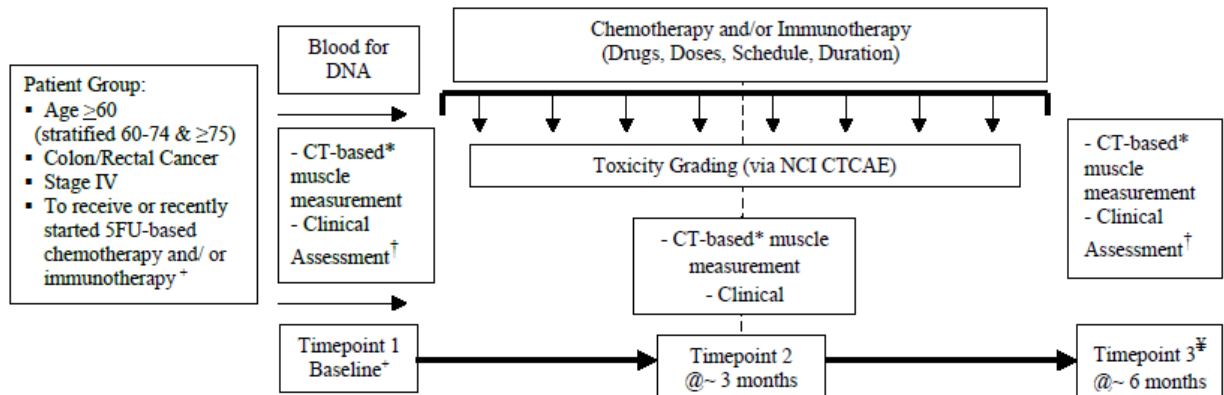
1. Older adults (age \geq 60y) with either
 - newly diagnosed metastatic CRC or
 - newly recognized metastatic recurrence of CRC \geq 3 months (12 weeks) from completion of treatment for non-metastatic CRC
2. Planning to or recently started to undergo immunotherapy and/or 5-FU based chemotherapy as first line of treatment. 5-FU chemotherapy can be 5-FU alone or in combination with oxaliplatin and/or irinotecan; +/- immunotherapy. Capecitabine is also acceptable. If unable to engage patient before treatment starts, enrollment is allowed up to four weeks after the start of treatment but must be before Cycle 2 begins.
3. Estimated life expectancy \geq 6 months.
4. Patients must be able to comprehend English or Spanish (for questionnaire completion).
5. Ability to understand and the willingness to sign a written informed consent document.
6. Patient eligibility is not dependent on BMI or weight. Patients with a significant ($\pm > 10\%$) body weight change in the previous 12 months are eligible for this study.

Exclusion Criteria

1. Patients enrolled on hospice
2. Prior systemic chemotherapy for metastatic colorectal cancer (acceptable if adjuvant chemotherapy completed \geq 3 months (12 weeks) prior to this disease recurrence and treatment).
3. Patients may not be receiving any other investigational agents. (For clarity, participants on the Alliance A021703 trial are also eligible for this study.)
4. No untreated brain metastases. Patients with treated brain metastases are eligible.
5. Patients on or planned to undergo radiation therapy in near future

SCHEMA

Study Design: This is a prospective cohort study that examines the impact of myopenia on toxicity and overall survival (OS) in older adults with newly diagnosed metastatic colorectal cancer (CRC) or newly recognized metastatic recurrence for CRC ≥ 3 months (12 weeks) from completion of treatment of non-metastatic CRC planning to or recently started to receive systemic chemotherapy and/or immunotherapy. The study also explores the moderating influence of genetic variation in the association between myopenia and toxicity.



*CT imaging is performed as part of routine care at baseline and every ~12 weeks during chemotherapy and/or immunotherapy to assess disease response.

[†]Clinical assessments include muscle strength, physical performance, questionnaire assessments, and PRO-CTCAE toxicity assessments.

[‡] Patients will be followed up to 1 year after diagnosis for survival only.

⁺ If unable to engage patient before treatment starts, enrollment is allowed up to four weeks after the start of treatment but must be before Cycle 2 begins.