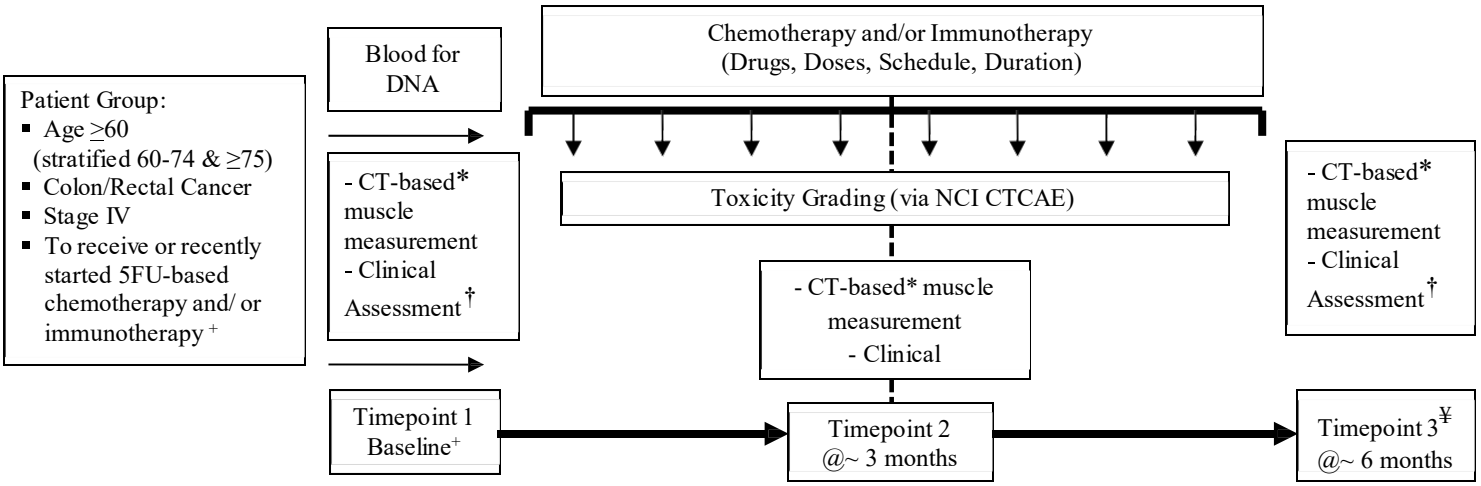
Cancer Research for the Ozarks

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 greater than ≥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.

Stratification: In order to ensure a wide range in body composition and a diverse sample of older adults, enrollment will occur in two age strata: 60-74yo and ≥75yo, with approximately 40% of those enrolled ≥75yo.

Study Sample: n=300 (approximately 40% of those enrolled ≥75yo)

Study Duration: 3.5 years

Brief Eligibility Criteria:

1) Older adults (age ≥60y) with either newly diagnosed metastatic CRC or newly recognized metastatic recurrence of CRC ≥3 months (12 weeks) from completion of treatment of 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 ≥6 months. Patients enrolled on hospice are ineligible.

4. PARTICIPANT SELECTION

4.1 Inclusion Criteria

4.1.1 Older adults (age ≥ 60y) with either

- newly diagnosed metastatic CRC or
- newly recognized metastatic recurrence of CRC ≥3 months (12 weeks) from completion of treatment for non-metastatic CRC

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.

4.1.2 Estimated life expectancy ≥ 6 months.

4.1.3 Patients must be able to comprehend English or Spanish (for questionnaire completion).

4.1.4 Ability to understand and the willingness to sign a written informed consent document.

4.1.5 Patient eligibility is not dependent on BMI or weight. Patients with a significant (± > 10%) body weight change in the previous 12 months are eligible for this study.

4.2 Exclusion Criteria

4.2.1 Patients enrolled on hospice.

4.2.2 Prior systemic chemotherapy for metastatic colorectal cancer (acceptable if adjuvant chemotherapy completed ≥3 months (12 weeks) prior to this disease recurrence and treatment).

4.2.3 Patients may not be receiving any other investigational agents (For clarity, participants on the Alliance A021703 trial are also eligible for this study).

4.2.4 No untreated brain metastases. Patients with treated brain metastases are eligible.

4.2.5 Patients on or planned to undergo radiation therapy in near future.

4.3 Inclusion of Women and Minorities

Both men and women (as applicable) and members of all races and ethnic groups are eligible for this trial. All questionnaires will be available in English and Spanish. We will encourage participating practices to approach all potentially eligible patients, regardless of gender or race/ethnicity. All Minority-Underserved NCORPs affiliated with the Wake Forest NCORP Research Base (WF NCORP RB) will be informed of the study and will be invited to participate. We will emphasize the importance of robust minority accrual at our study kickoff meetings and provide specific education and discussion about strategies to overcome barriers that underserved patients may experience to study participation. Leaders of the Wake Forest Baptist Comprehensive Cancer Center Office of Cancer Health Equity will facilitate this aspect of training and have provided feedback on our recruitment strategy. We will also ask participating Minority-Underserved NCORPs to provide suggestions about strategies for approaching and consenting racial/ethnic minority patients. We will monitor minority recruitment rates at our monthly WF NCORP RB Executive Steering Committee meetings and provide feedback to the NCORP sites via bi-monthly study teleconference calls. Specifically, we will monitor the minority recruitment rate in conjunction with available data about the population of patients to identify sites that are potentially under and over performing with regards to minority accrual. Sites with strong minority recruitment will be asked to share their experiences with other sites during these calls.