Using ctDNA Methylation to Monitor Metastatic Colorectal Cancer Treatment (PROMET)

NCT07283575

Status	RECRUITING
Sponsor	Fudan University
Enrollment	497 participants

Plain Language Summary

This study is testing whether measuring methylation patterns in circulating tumor DNA (cancer DNA found in the bloodstream) can help doctors better track how well treatment is working in patients with metastatic or recurrent colorectal cancer.

You may be eligible if...
- You are 18 or older
- You have been confirmed by biopsy to have recurrent or metastatic colorectal cancer
- You are eligible to receive radiation therapy combined with standard chemotherapy, with or without immunotherapy (PD-1 inhibitors)
- You are expected to survive at least 6 months
- You (or your legal representative) are willing to sign an informed consent form

You may NOT be eligible if...
- You received a blood transfusion during surgery or within 2 weeks before the study
- You are pregnant or breastfeeding without using adequate contraception
- You have a history of other cancers
- Your condition or treatment plan does not meet the study's requirements

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

Key Eligibility Criteria

Inclusion (5)

- Age e 18 years old, regardless of gender;
- Histologically confirmed, recurrent or metastatic colorectal cancer;
- Eligible to receive radiotherapy in combination with standard-of-care chemotherapy, with or without PD-1 inhibitors.
- With expected survival of more than 6 months;
- The subjects (or their legal representative / Guardian) must sign the informed consent form, indicating that they understand the purpose of the study, understand the necessary procedures of the study, and are willing to participate in the study.

Exclusion (7)

- Blood transfusion performed during operation or within 2 weeks before operation;
- Pregnant or lactating women who have fertility and do not take adequate contraceptive measures;
- Have a history of other malignant tumors within 5 years, except cured cervical carcinoma in situ or non melanoma skin cancer;
- Primary brain tumor or central nerve metastasis is not under control, with obvious intracranial hypertension or neuropsychiatric symptoms;
- Patients with the following serious or uncontrollable diseases: severe heart disease, the condition is still unstable after treatment, including myocardial infarction, congestive heart failure, unstable angina pectoris, pericardial effusion with obvious symptoms or unstable arrhythmia within 6 months before enrollment; definite neuropathy or psychosis, including dementia or seizures; severe or uncontrolled infection; active disseminated intravascular coagulation and obvious bleeding tendency;

... and 2 more (see full listing online)

Locations (1 total)

Fudan University Shanghai Cancer Center, Shanghai, China