A Prospective Feasibility Study Using ctDNA to Tailor Neoadjuvant Chemotherapy for Patients With Colorectal or Appendiceal Adenocarcinoma

NCT05947838

Status	RECRUITING
Phase	Not Applicable
Sponsor	M.D. Anderson Cancer Center
Enrollment	48 participants

Plain Language Summary

This study is investigating whether a blood test that detects tumor DNA (called ctDNA) can help doctors personalize chemotherapy decisions for patients with colorectal or appendix cancer that has spread to the lining of the abdomen (peritoneal metastases). The goal is to see if tailoring treatment based on this test improves outcomes.

You may be eligible if...
- You are 18 or older with a confirmed diagnosis of colorectal or appendiceal cancer that has spread to the abdomen's lining
- Your cancer is potentially removable by surgery
- Your overall health (ECOG 0–1) allows for chemotherapy
- You have adequate blood counts, liver, and kidney function

You may NOT be eligible if...
- Your cancer has also spread to the brain, liver, or lungs
- You have had serious complications from prior chemotherapy
- You have uncontrolled medical or psychiatric conditions
- You are pregnant or breastfeeding

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

Key Eligibility Criteria

Inclusion (22)

- Histologically/cytologically confirmed diagnosis of moderate or poorly differentiated appendiceal or colorectal adenocarcinoma of any grade with Initial resectable disease.
- Have metastatic peritoneal disease that is visible on imaging or at the time of laparoscopy.
- Age e18 years. Because no adverse event data are currently available on the use of ctDNA in chemotherapy decision making in patients \<18 years of age, children are excluded from this study.
- ECOG performance status d1 (Karnofsky e70%,).
- Patients must have adequate organ and marrow function as defined below:

... and 17 more (see full listing online)

Exclusion (9)

- Patients who have not recovered from adverse events due to prior anti-cancer therapy (i.e., have residual toxicities \> Grade 1) with the exception of alopecia.
- Patients who are receiving any other investigational agents.
- Patients with brain or other visceral (i.e. liver and/or lung) metastases at the discretion of the investigator.
- Patients with uncontrolled intercurrent illness (Indicate clearly what type or extent)

- Patients with psychiatric illness/social situations that would limit compliance with study requirements.

... and 4 more (see full listing online)

Locations (1 total)

M D Anderson Cancer Center, Houston, Texas, United States