Individual Response to Hyperthermic Intraperitoneal Chemotherapy (HIPEC) Treatment of Peritoneal Carcinomatosis From Peritoneal Mesothelioma or Atypical Mesothelial Proliferation or From Ovarian, Colorectal, or Appendiceal Histologies

NCT04847063

Status	RECRUITING
Phase	Phase 1
Sponsor	National Cancer Institute (NCI)
Enrollment	60 participants

Plain Language Summary

This study is testing a personalized version of heated chemotherapy delivered directly into the abdomen during surgery (called HIPEC) for people whose cancer has spread to the lining of the abdominal cavity — originating from the ovaries, colon, appendix, or the abdominal lining itself (peritoneal mesothelioma).

You may be eligible if:
- You have confirmed cancer spreading along the inside of the abdomen from one of the above origins
- Your surgeon believes all the cancer can be surgically removed
- Your cancer spread is not too extensive (assessed by a laparoscopic scoring system)
- You are 18 or older in generally good health (ECOG 0–1)
- Your blood counts, kidney, and liver function are adequate

You may NOT be eligible if:
- Your cancer has spread outside the abdomen to distant sites
- You have had major abdominal surgery in the past 12 weeks or intraperitoneal chemotherapy in the past 4 weeks
- You have a known allergy to platinum-based chemotherapy
- You are pregnant or breastfeeding
- You have HIV with a detectable viral load not controlled by antiretrovirals

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

Key Eligibility Criteria

Inclusion (18)

- Confirmation of peritoneal carcinomatosis from peritoneal mesothelioma or atypical mesothelial proliferation, or from appendiceal, colorectal, or ovarian, histologies by the Laboratory of Pathology, NCI.
- Measurable or evaluable disease as defined by RECIST v1.1. criteria and/or by peritoneal carcinomatosis index (PCI) score.
- Participants must be assessed to be able to undergo optimal cytoreduction (i.e., completeness of cytoreduction score of 1 or 0) with laparoscopically assessed PCI score threshold as indicated below:
- Primary Histology: Appendiceal/Colorectal/Ovarian / PCI Cutoff for Eligibility: Total Score \< 20 (out of 39 possible points)
- Primary Histology: Mesothelioma or atypical mesothelial proliferation / PCI Cutoff for Eligibility: Total Score \<= 30 (out of 39 possible points)

... and 13 more (see full listing online)

Exclusion (8)

- Participants with known extra-abdominal metastatic disease from the participant s appendiceal, colorectal, ovarian, or peritoneal mesothelioma primary

• Participants who have received intraperitoneal chemotherapy or other anti-cancer therapy within the last 4 weeks prior to the start of study treatment.

• Participants who have undergone major surgery within the last 12 weeks prior to the start of study treatment.

• History of allergic reactions attributed to platinum-containing compounds.

• History of dihydropyrimidine dehydrogenase deficiency (only participants with appendiceal or colorectal cancer).

... and 3 more (see full listing online)

Locations (1 total)

National Institutes of Health Clinical Center, Bethesda, Maryland, United States