

PI: Emily Kinsey, MD

Academic Rank: Assistant Professor

Department: Internal Medicine / Hematology, Oncology and Palliative Care

Title: A Pilot Study to Evaluate the Efficacy and Safety of the Addition of Ciprofloxacin, Metronidazole, and Aspirin in Addition to Chemotherapy in Patients Undergoing First Line Therapy for Metastatic Colorectal Cancer

The bacteria living in our intestines (the microbiome) plays a role in cancer development, cancer growth, and drug resistance. Two specific bacteria, *F.nucleatum* and *pks+ E.coli* may be harmful in patients with cancer. It has been suggested that we may be able to target the microbiome, attempt to eradicate these cancer-associated bacteria, and lead to better outcomes for patients. It is not known, however, what happens to these bacteria with the addition of standard of care chemotherapy in patients embarking on treatment in the first line setting for metastatic colorectal cancer. This project aims to further understand the gut microbiome in patients with colon cancer who are undergoing treatment and specifically quantify the changes in two specific cancer-associated bacteria.

We will test stool studies to look at the various bacteria present in the stool at two time points in up to 18 patients with stage IV, metastatic, colorectal cancer. Our first time point of testing stool will be prior to receiving any chemotherapy treatment. Our second time point of testing stool will be after about 1 month, or two cycles, of chemotherapy treatment. We will compare these two time points in each patient to see if the amount of cancer associated bacteria will decrease with chemotherapy alone. We will also look at all the bacteria present and determine if any significant changes occur with chemotherapy. Finally, we will look at the bacteria in the tumor taken during colonoscopy and compare it to the baseline stool sample. This will help us to understand the microbiome and what changes occur during standard of care cancer treatment and if the bacteria present in the stool are representative of the bacteria present in the tumor. We will be able to use this information to design larger trials which will potentially be able to target the microbiome for treatment.