

Evaluating the Association Among Changes in Gut Microbiome, Fatigue, and Chemotherapy-Induced Nausea in Early Stage Breast Cancer

NCT05417867

Status	RECRUITING
Sponsor	Mayo Clinic
Enrollment	70 participants

Plain Language Summary

This study is examining whether changes in the gut microbiome (the community of bacteria in the digestive tract) are linked to nausea and fatigue during chemotherapy in people with early-stage breast cancer. Understanding this connection may help develop ways to reduce these distressing side effects.

You may be eligible if...

- You have been diagnosed with early-stage breast cancer
- You are scheduled to receive chemotherapy that has a moderate to high risk of causing nausea (emetogenic chemotherapy)
- You are being treated at a Mayo Clinic site

You may NOT be eligible if...

- You have received prior chemotherapy for breast cancer
- You have a chronic gastrointestinal condition (like Crohn's disease or IBS)
- You have taken antibiotics recently (usually within 30 days)
- You use probiotics regularly
- You are pregnant

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

Key Eligibility Criteria

Inclusion (4)

- Subjects with a diagnosis of early stage breast cancer planning to receive moderate to highly emetogenic chemotherapy will be recruited at Mayo Clinic Health Systems including Mankato and Albert Lea; Mayo Clinic Arizona; Mayo Clinic Rochester (Minnesota); and Mayo Clinic Florida
- At least 20 years of age
- Last chemotherapy more than 3 years ago
- Scheduled to receive moderate to highly emetogenic chemotherapy with or without targeted therapies including immunotherapies

Exclusion (3)

- Metastatic disease
- Concurrent radiation therapy
- Concurrent antibiotic treatment

Locations (5 total)

Mayo Clinic in Arizona, Scottsdale, Arizona, United States

<https://www.mayoclinic.org/locations/locations-in-florida/nct05417867>

Mayo Clinic Health System in Albert Lea, Albert Lea, Minnesota, United States

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... and 2 more locations

<https://clinicaltrials.gov/study/NCT05417867>

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