COMING SOON!

A randomized pragmatic trial of genotype-guided supportive care in symptom treatment of cancer patients

OVERVIEW
This is a single center, pilot randomized pragmatic clinical trial (PCT) of 500 patients who are undergoing chemotherapy for newly diagnosed or recurrent cancers.

All patients in this study will undergo genotyping for several genes that are associated with drug-metabolizing enzymes for drugs commonly used in supportive care regimens. Patients will be randomized to have their genotype results returned immediately or returned after 12 weeks. Supportive care regimens may include therapies for antiemesis, pain management, GI protection, antidepressants, antifungal prophylaxis, and anticoagulants.

For those patients randomized to the immediate return of genotype results, the genotype results will be returned in Epic and supportive care will be prescribed based on these results. For those randomized to the delayed genotype intervention group, supportive care will be prescribed based on usual clinical practice. Participation is expected to last approximately 12 weeks and the study will be open for 30-36 months.

PRIMARY OBJECTIVE
Evaluating patient-reported symptom distress is the primary objective of this study, and patients will complete a validated MD Anderson Symptom Inventory (MDASI) questionnaire at multiple time points during the study.

QUESTIONS?
For more information about this trial (NCT03924557), contact Dr. Thomas George, MD, FACP at thom.george@medicine.ufl.edu or Dr. Cooper-DeHoff, PharmD, MS, at Dehoff@cop.ufl.edu.

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STUDY SCHEMA

Assessed for eligibility

Randomization (n=500)

Genotyping Intervention (n=250)
- Preemptive genotype results and consult placed in EHR
- Genotype guided supportive care treatment regimen prescribed

Delayed Genotyping Intervention (n=250)
- Blood sample held for delayed genotyping
- Supportive care treatment regimen prescribed

Initiate Chemotherapy

Primary Endpoint
- Composite MDASI 2 wks. after chemo initiation

Follow-up
- Repeat MDASI 4 wks. and 12 wks. after chemo initiation

Run genotype panel (12 wks. after initiating chemo)
- Results and consult placed in EHR
- Patient followed for medication change based on genotype results