Doctor's Note — Clinical Trial Summary

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TRIAL

Diet and Immune Effects Trial: DIET- A Randomized Double Blinded Dietary Intervention Study in Patients With Metastatic Melanoma Receiving Immunotherapy

NCT ID: NCT04645680 Phase: PHASE2 Sponsor: M.D. Anderson Cancer Center Status: Active Not Recruiting

SUMMARY

This is a randomized, double-blind, fully controlled feeding study that will enroll melanoma patients starting standard-of-care ICB in three settings: adjuvant, neoadjuvant, and unresectable. Patients are randomized to the high fiber or healthy control diet. The goal of the study is to establish the effects of dietary intervention on the structure and function of the gut microbiome in patients with melanoma treated with SOC immunotherapies.

KEY ELIGIBILITY CRITERIA

- 1. Age e 18 years old.
- 2. Body mass index (BMI) 18.5-40 kg/m\^2
- 3. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- 4. English-speaking
- 5. Self-reported willingness to exclusively eat the provided diets
- 6. Self-reported willingness to comply with scheduled visits, undergo venipuncture, and provide stool samples
- 7. Cohort-specific:
- * 1 Adjuvant Melanoma: i. Resected Stage II-IV melanoma with planned initiation of adjuvant anti-PD1 +/- anti-CTLA4 or anti-LAG3
- * 2 Unresectable Melanoma: i. Histologically confirmed unresectable stage III or Stage IV melanoma with planned initiation of standard of care anti-PD1 +/- CTLA4 or anti-PD1 +/- LAG3 immunotherapy and no prior immunotherapy in the metastatic setting.
- * 3 Neoadjuvant Melanoma: i. Histologically confirmed stage III/IV melanoma with planned initiation of neoadjuvant anti-PD1 +/- anti-CTLA4 or anti-LAG3 1. Participants must have archival tissue block available or be willing to undergo a newly-obtained core needle or incisional biopsy at baseline. Fine needle aspiration is not acceptable.

Total sites: 1 | 0 currently recruiting