

Effect of Kava on Anxiety and Stress in Cancer Survivors

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Adult \geq 18 years old - Completed curative-intent treatment for breast, gynecologic, lung, or head/neck cancer within the last 24 months without clinical and/or radiographic evidence of recurrence at the time of the last follow up - Willing to abstain from benzodiazepine and alcohol use during the kava or placebo intervention and for at least 14 days after completion

Exclusion Criteria:

- Known allergy to kava - Regular use of benzodiazepines, defined as \geq 2 times weekly, within 14 days prior to study registration - Use of herbal supplements within 14 days of study registration, - Anti-cancer therapy within 28 days prior to registration and/or during study participation, except for aromatase inhibitors - Known liver disease such as cirrhosis - Use of acetaminophen at doses more than 2000 mg daily for more than three days per week within 7 days prior to the first dose of kava or placebo intervention - Chronic use of high-intensity statin therapy - Women who are pregnant, intend to become pregnant, or are nursing

Conditions & Interventions

Conditions:

Cancer

Keywords:

anxiety, cancer survivor, Clinics and Surgery Center (CSC), kava

More Information

Description: This is a pilot, two-arm, randomized, blinded, placebo-controlled cross-over design to test the safety and efficacy of a 14-day course of kava in reducing anxiety and stress in adult cancer survivors. The primary objectives of this study are: 1) determine the effect of kava on anxiety in cancer survivors using the PROMIS anxiety score; and 2) determine the safety of kava in cancer survivors using CTCAE v5.0.

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Phase: EARLY_PHASE1

IRB

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