Citrus AntiFatigue Powder

Study Proposal

With approximately 14 million cancer survivors today in the United States alone, increased attention is being given to the quality of life of our cancer patients both during and after treatment. Cancer related fatigue (CRF) is the most common, and one of the most devastating symptoms among patients with cancer (Bruera, 2012). According to the National Comprehensive Cancer Network, CRF is defined as a "persistent, subjective sense of physical, emotional, and/or cognitive exhaustion related to cancer or its treatment that is not proportional to recent activity" (NCCN, 2008). CRF has been rated as having a greater negative impact on quality of life than other cancer-related symptoms such as pain, depression, and nausea (Hoffman, 2007). In addition, CRF has a negative impact on all areas of function, including mood, physical function, work performance, social interaction, family care, cognitive performance, schoolwork, and community activities (Berger, 2009; Bower, 2005; NCI, 2010). Unfortunately, clinically meaningful, evidence-based treatment options for CRF are extremely limited. A supplement that can be taken orally to mitigate CRF would represent a tremendous contribution towards the care of our patients affected with cancer and potentially for people with other causes of fatigue.

A recent phase III clinical trial found a statistically significant improvement in fatigue after 4 weeks of American ginseng. This pilot study seeks to evaluate the viability of Citrus AntiFatigue Powder for CRF.

Objective: To determine if Citrus AntiFatigue powder is effective in improving CRF as measured by the FACIT-F and the PROMIS Item Bank – Fatigue – Short Form.

Design: Randomized placebo-controlled pilot study

Setting: Comprehensive outpatient cancer center

Methods: Forty cancer patients to be randomized to Citrus AntiFatigue powder (daily? BID?) versus placebo for eight weeks.

Inclusion criteria:

- Adult cancer survivors (>18 years)
- All tumor types with the exception of patients with brain tumor or central nervous system metastasis to improve external validity
- Patients actively receiving chemotherapy or radiation treatment for curative intent or have completed treatment within the last 12 months
- Baseline CRF score of >5/10 (on an 11-point scale where 0 is "no fatigue" and 10 equal to "worst fatigue imaginable".

Exclusion criteria:

- Those who have previously used ginseng, glutamine, or caffeine or other agents for fatigue for 4 weeks prior to the start of the study are not eligible.
- Change in chemotherapy or radiation therapy plans during the study period
- Brain tumors or central nervous system metastasis
- Anemia (hemoglobin <8.0 gm/dl), hypothyroidism, or other medical comorbidities that are felt to contribute to fatigue

Outcome Measures:

- Assessments to be carried out at baseline, 4 weeks, and 8 weeks.
- Assessment tools would include:
    - FACIT-F
    - PROMIS Item Bank – Fatigue – Short Form
    - Common Terminology Criteria for Adverse Events (CTCAE) to evaluate for any toxicities related to Citrus AntiFatigue powder.