

Research May Help Determine if Flaxseed Benefits Women with Ovarian Cancer

Why is this study being done?

The goal of this study is to determine if women who have been diagnosed with ovarian cancer, and are currently in remission, can tolerate 20g per day (approximately 3 tablespoons) of ground flaxseed as a dietary supplement. Flaxseeds contain a good amount of fiber, phytoestrogens (lignans) and omega-3 fatty acids (fats that are found in plant or fish products). Lignans and omega-3 fatty acids have been widely studied and are known for various health benefits, including reducing the risk of cardiovascular disease and inflammation. Investigators from our institution have completed studies that suggest flaxseed can slow the growth of ovarian cancer in hens (an appropriate animal model for human ovarian cancer). Thus, they believe that dietary supplementation with flaxseed could help prolong the disease-free interval and possibly prevent recurrence of ovarian cancer. The addition of flaxseed to a healthy diet is currently being investigated in numerous clinical trials; however, this will be the first study to examine the effects of flaxseed supplementation in women who have been diagnosed with ovarian cancer.

Who is eligible for this study?

- Patients age \geq 21 years
- Patients with a diagnosis of ovarian cancer including epithelial ovarian carcinoma, primary peritoneal cancer or fallopian tube cancer who are currently in clinical remission as determined by their gynecologist/oncologist
- Those at risk of clinical relapse: patients of any stage who are in remission from ovarian cancer who have previously undergone surgical debulking and adjuvant chemotherapy
- Eligible patients must have adequate bone marrow function, renal function and hepatic function

What will happen if you take part in this research study?

Before you begin the study...

- Your gynecologic oncology physician will perform a physical exam and a review of your level of activity and your blood test results to ensure that you are in remission. This will be done as a part of your routine care during your post-chemotherapy visit.

During the study...

- You will be required to consume 20g (approximately 3 tablespoons) of ground flaxseed per day for two years (24 months). Sealed individual packets will be provided to you.
- You will be required to record your daily flaxseed and fluid intake on a monthly dietary log.
- You will return to the SIU Gynecologic Oncology office every 3 months (as part of your standard treatment and surveillance) to see your physician, you will return any unused portion of your flaxseed supply and review your dietary and fluid logs.
- You will be asked to donate a urine sample and an additional tube of blood for research at each of your follow-up visits (every 3 months) for two years after the initiation of the study.
- You will be required to complete a survey regarding your physical, social, emotional and functional well-being. You will repeat the same survey after one year of flaxseed supplementation and then again at your last visit.

For more information, go to: clinicaltrials.gov, search for: NCT02324439

Please feel free to contact our study team with any questions:

Kathleen Groesch, MS, CCRP

(217) 545-6671

kgroesch@siumed.edu

Paula Diaz-Sylvester, PhD

(217) 545-5982

pdiaz-sylvester@siumed.edu

Laurent Brard, MD, PhD

(217) 545-8882

lbrard@siumed.edu

Terri Wilson, BA

(217) 545-6711

twilson2@siumed.edu

