A Randomized Phase II Study of Letrozole Versus Observation in Patients with Newly Diagnosed Uterine Leiomyosarcoma

Status: Recruiting

Eligibility Criteria

Sex: Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- confirmed newly diagnosed uterine leiomyosarcoma with disease limited to the uterus - tumor expresses ER positivity by immunohistochemistry - completed hysterectomy and bilateral salpingo-oopherectomy no more than 12 weeks prior - walking and able to do all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours - able to swallow oral medication - see link to clinicaltrials.gov for complete inclusion criteria

Exclusion Criteria:

- any other severe disease - also has another cancer or has been treated for cancer in the past three years - women who are pregnant or breastfeeding - currently receiving chemotherapy or radiation therapy - see link to clinicaltrials.gov for complete exclusion criteria

Conditions & Interventions

Interventions:
Drug: Letrozole
Conditions:
Cancer, Women's Health
Keywords:
Uterine Leiomyosarcoma, Clinics and Surgery Center (CSC)

More Information

Description: The purpose of this study is to find out if the drug letrozole is better or worse than not receiving treatment (called observation) following surgery for your type of cancer. Letrozole could prevent your cancer from returning but the cancer could grow while on treatment. There is currently no definitive data to support the use of Letrozole treatment for early stage Leiomyosarcoma. Letrozole has already been FDA-approved to treat other cancers, but it is investigational in this research.
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