

NRG-GY028: A PHASE IB AND RANDOMIZED PHASE II TRIAL OF MEGESTROL ACETATE WITH OR WITHOUT IPATASERTIB IN RECURRENT OR METASTATIC ENDOMETRIOID ENDOMETRIAL CANCER

Status: Recruiting

Eligibility Criteria

Sex: Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- diagnosis of grade 1 or 2 recurrent or metastatic endometrioid endometrial cancer - may have received unlimited prior lines of therapy - walking and able to do all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours - must be able to swallow and retain oral medications and not have gastrointestinal illnesses that would preclude absorption of medications - must agree to use adequate contraception during study therapy and for 28 days following the last dose of study therapy - see link to clinicaltrials.gov for complete inclusion and exclusion criteria

Exclusion Criteria:

- diabetes either requiring insulin therapy or with a baseline fasting glucose > 160 mg/dL and/or high glycosylated hemoglobin A1c (HbA1c) (> 8) - require chronic corticosteroid therapy of > 10 mg of prednisone per day or an equivalent dose of other anti-inflammatory corticosteroids or immunosuppressant agents for a chronic disease - history of known or active inflammatory bowel disease (e.g., Crohn disease and ulcerative colitis) or active bowel inflammation (e.g., diverticulitis) - clinically significant history of liver disease - women who are pregnant or breast feeding

Conditions & Interventions

Interventions:

Procedure: Biospecimen Collection, Procedure: Computed Tomography, Drug: Ipatasertib, Procedure: Magnetic Resonance Imaging, Drug: Megestrol Acetate

Conditions:

Cancer

More Information

Description: This trial tests the safety, side effects, best dose, and effectiveness of the combination of ipatasertib with megestrol acetate to megestrol acetate alone in women who have endometrial cancer that has come back (recurrent) or has spread to other places in the body (metastatic). Ipatasertib may stop the growth of tumor cells and may kill them by blocking some of the enzymes needed for cell growth. Megestrol acetate lowers the amount of estrogen and also blocks the use of estrogen made by the body. This may help stop the growth of tumor cells that need estrogen to grow. The combination of ipatasertib and megestrol acetate may be more effective in treating endometrial cancer than megestrol acetate alone.

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Phase: PHASE1

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