Surgical Window of Opportunity Study of Megestrol Acetate Compared with Megestrol Acetate and Metformin for Endometrial Intraepithelial Neoplasia

Status: Recruiting

Eligibility Criteria

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

Inclusion Criteria:

- endometrial intraepithelial neoplasia (EIN) on an endometrial biopsy or dilation and curettage specimen - willing to have surgery (hysterectomy) or non-surgical treatment with a progestin IUD - if diabetic, blood glucose must be appropriately controlled as evidenced by a hemoglobin A1c of < 8.0 in the last three months prior to enrollment - women of child-bearing potential must agree to use adequate contraception (barrier method of birth control; abstinence) prior to study entry and for the duration of study participation

Exclusion Criteria:

- Current hormonal contraceptives or post-menopausal hormone replacement therapy, and uses of progestins (including progestin containing intrauterine device (there are exceptions, study staff will review) - current use of metformin therapy. If previously used, it must be discontinued at least a year ago - women who are pregnant or breast feeding - history of pulmonary embolism, thrombotic stroke, arterial thrombosis or deep vein thrombosis - see link to clinicaltrials.gov for additional inclusion and exclusion criteria

Conditions & Interventions

Conditions:
Cancer
Keywords:
Clinics and Surgery Center (CSC), Endometrial Carcinoma, endometrial intraepithelial neoplasia (EIN)

More Information

Description: The purpose of this study is to compare the effectiveness of megestrol alone, or combined with metformin, on the growth of Endometrial Intraepithelial Neoplasia (EIN). Participants will receive medication directed against EIN prior to the planned procedure (hysterectomy or progestin IUD placement). Women will receive either megestrol acetate pills by mouth twice a day for 3 to 5 weeks, or megestrol acetate and metformin pills twice a day by mouth for 3 to 5 weeks.
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