A clinical trial for patients with clear cell or endometrioid ovarian or endometrial cancer which has returned or spread after other treatments

NRG ONCOLOGY

Advancing Research. Improving Lives.™

ABOUT THE TRIAL

NRG-GY031 is a clinical trial for patients with clear cell or endometrioid ovarian or endometrial cancer which has returned or spread after other treatments. Patients with platinum-resistant high grade serous ovarian cancer are also allowed to enroll on Part I of this study. This Phase I trial will test a new combination of two medications, M1774 and ZEN003694, that has been shown to significantly kill cancer cells and tumors in animal studies. The study is divided into two parts. In Part I, different drug combination doses are tested to identify the safe dose for patients. In Part II, we will continue to evaluate safety of the treatment, but also activity of the treatment in two groups of patients, those with and without a mutation in the gene *ARID1A*. The ultimate goal of this study is to identify a new treatment for patients with hard to treat ovarian and endometrial cancers.

ABOUT NRG ONCOLOGY

As one of the five research groups in the National Cancer Institute's (NCI) National Clinical Trials Network (NCTN), NRG Oncology carries out clinical trials on sex-specific malignancies, including gynecologic, breast, and prostate cancers, and on localized or locally advanced cancers of all types. NRG Oncology's extensive research organization includes investigators, medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians. The NRG Oncology includes more than 1,300 research sites worldwide, primarily in the United States and Canada. NRG Oncology is a non-profit research organization, funded mainly through grants from the NCI. To contact NRG Oncology, call 267-519-6630 or email info@nrgoncology.org

Frequently Asked Questions

What is a clinical trial?
Clinical trials are research studies that look to find better ways to prevent, diagnose, or treat disease.

Who can join this study?
Patients who have clear cell ovarian or endometrial cancer or endometrioid ovarian or endometrial cancer that has returned or spread after other treatments. Patients with platinum resistant high grade serous ovarian carcinoma may join the first part of this study.

Am I required to be in this study?
No. Taking part in this study is voluntary. You are free to choose to participate or not to participate. If you choose to participate in this study, you are able to leave the study at any time. If you decide not to take part in this study, your doctor will discuss other treatment options with you.

What is the goal of this study?
This is a Phase I study, which means the goal is to identify which dose of a treatment is safest for patients. We know from cell and animal studies this treatment is safe and effective. This combination targets two essential pathways common in these cancers. We now plan to test if this is safe and active in humans.

Can I change my mind if I choose to take part in this study?
Yes. Taking part in this study is voluntary. If you choose to participate in this study, you can leave the study at any time. If you decide not to take part in this study, your doctor will discuss other treatment options with you.

What are the possible treatments?
The goal of Part I is to find the safest dose of this new treatment combination: M1774 – an ATR inhibitor and ZEN003694 – a BET inhibitor. Both drugs are oral medications (pills). If you are in Part I, you will be treated with a combination of two drugs (M1774 and ZEN003694). If the combination dose given to you causes side effects that are too severe, the dose of the medications will be lowered. Multiple dose levels will be tested in Part I.

Part II has two study groups, a group of patients with a mutation in a gene called *ARID1A* and a group of patients without a mutation in *ARID1A*. Both groups will receive the same dose of medication. The study is investigating if this gene mutation affects how a patient's tumor responds to the treatment.

What is required to be in the study?
You will take the prescribed dose of medications. There will be frequent blood tests. In Part II, two biopsies are required: a biopsy before starting the study treatment and a biopsy during the study.

How long will I be in this study?
You will continue to receive your assigned treatment until your disease stops responding to treatment or you have unacceptable side effects. The study team will follow you for up to five years after you finish treatment.

Are there side effects?
There may be. The most common side effects of M1774 include nausea/vomiting, fatigue, anemia, and thrombocytopenia (low platelets). The most common side effects of ZEN003694 include temporary vision change (seeing bright lights and/or difficulty navigating in dim light), nausea, decreased appetite, change in taste, constipation, fatigue, thrombocytopenia (low platelets), and bruising/bleeding.

There may be some side effects that the study doctors do not yet know about. Your doctor will review all the potential side effects with you.

Nurse Support Contact: *Perelmangyn/onc/researchnursepool@PennMedicine.upenn.edu*

ClinicalTrials.gov Identifier: *NCT05950464*

MORE INFORMATION

Visit the National Cancer Institute website at https://www.cancer.gov for more information about studies or general information about cancer.
You may also call: 1-(800)-4-CANCER (1-800-422-6237).