ForPatients
by Roche

Endometrial Cancer

A clinical trial to look at how well giredestrant works in people with Stage 1, Grade 1 endometrial cancer, how safe giredestrant is and to understand the way the body processes giredestrant

A Study of Giredestrant in Participants With Grade 1 Endometrial Cancer

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	4 Countries	NCT05634499 2022-002443-21 CO44195

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This Phase II, global, single-arm study is designed to evaluate the efficacy, safety, and pharmacokinetics of giredestrant monotherapy in participants with Grade 1 endometrioid endometrial cancer.

Hoffmann-La Roche Sponsor	**Phase 2** Phase

NCT05634499 2022-002443-21 CO44195
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Female	>=18 Years	No

1. Why is the endomERA clinical trial needed?

The uterus (womb) is an organ where a baby is carried during pregnancy. The inner layer of the uterus is called the endometrium, or lining, and endometrial cancer occurs when the cells of this lining grow out of control. A high level of a hormone called oestrogen is one of the main things that drive endometrial cancer. Cancers are described based on how much and how fast they grow. Endometrial cancer that has not spread outside the uterus is known as ‘Stage 1’ endometrial cancer. ‘Grade 1’ endometrial cancer cells are similar to normal cells and tend to grow slowly. Endometrial cancer, which is Stage 1 and Grade 1, is considered low-risk.

Standard treatment for endometrial cancer is surgery to remove the uterus (hysterectomy). Women who have had a hysterectomy can no longer become pregnant. However, women who have been diagnosed with Grade 1 endometrial cancer and who are not able to or prefer not to have immediate surgery or who would like to have children can be offered hormone therapy to block oestrogen to delay surgery. Better oestrogen-blocking treatments are needed for people with endometrial cancer.

Giredestrant is a new drug designed to block oestrogen. Giredestrant is an experimental medicine, which means health authorities have not approved giredestrant for the treatment of endometrial cancer.

This clinical trial will look at the safety and effectiveness of giredestrant in people with Stage 1, Grade 1 endometrial cancer and how the body processes giredestrant.

2. How does the endomERA clinical trial work?

This clinical trial is recruiting people who have a health condition called Stage 1, Grade 1 endometrial cancer. People can take part if they have not previously received treatment for endometrial cancer or for conditions that can develop into endometrial cancer (known as endometrial hyperplasia and endometrial intraepithelial neoplasia), and they are willing to delay a hysterectomy for 6 months.

The purpose of this clinical trial is to look at the effects, good or bad, of giredestrant in participants with endometrial cancer and to understand how the body processes giredestrant.

Participants will be given the clinical trial treatment giredestrant as a pill (to be swallowed) once every day over 6 months, in 28-day treatment periods (called treatment ‘cycles’) until they have completed 6 treatment cycles. After 6 treatment cycles, participants and their clinical trial doctor can choose to be given alternative standard treatment (such as surgery) or to continue the clinical trial treatment for up to 18 more treatment cycles.

Participants will be seen by the clinical trial doctor on Day 1 of each treatment cycle, and 1 month after the last dose of clinical trial treatment has been given. These hospital visits will include checks to see how the participant is responding to the treatment (including by taking a sample of endometrium cells, known as a ‘biopsy’, at the start of the trial and at Months 3 and 6) and discussing any side effects they may be having. Participants’ total time in the clinical trial will be approximately 8 months to more than 2 years (26 months). Participants are free to stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the endomERA clinical trial?

The main clinical trial endpoints (the main results that are measured in the trial to see if the treatment has worked) are:

The number of participants who have a decrease in cancer cells or an increase in non-cancer or non-hyperplasia cells (known as ‘regression’) in a biopsy of their endometrium taken at Month 6 compared with the start of the trial, and

The number and seriousness of any side effects

The other clinical trial endpoints include:

How many participants have no cancer or hyperplasia cells in their biopsy at Month 6 (complete regression rate)

How much time is there between the participant’s first regression and the cancer getting worse

How much time is there between starting the trial treatment and the participant’s first regression

How much time is there between starting the trial treatment and the participant’s cancer getting worse

How the body processes giredestrant

4. Who can take part in this clinical trial?

People can take part in this trial if they are over 18 years of age and have been diagnosed with Stage 1, Grade 1 endometrial cancer. Participants must also be willing to be given clinical trial treatment for 6 months before a decision to have surgery is made and to have endometrial biopsies taken throughout the trial.

People may not be able to take part in this trial if they:

Have previously received treatment for endometrial cancer, endometrial hyperplasia or endometrial intraepithelial neoplasia

Have previously received other certain treatments, including treatments for cancer, such as chemotherapy, within a specific timeframe before starting the trial

Have certain other medical conditions, including conditions that affect the digestive system or liver, or certain infections

Are not able to swallow pills

Are pregnant or breastfeeding or are planning to become pregnant during the trial or within 10 days of completing the clinical trial treatment

5. What treatment will participants be given in this clinical trial?

Everyone who joins this clinical trial will be given giredestrant as a pill to be swallowed every day on Days 1–28 of each 28-day treatment cycle for at least 6 treatment cycles.

This is an ‘open-label’ clinical trial, which means that both participants and the clinical trial doctor will know which treatment participants have been given.

6. Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant, although it may not be greater than the risks related to routine medical care or the natural progression of the health condition. Potential participants will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. These will all be described in an informed consent document (a document that provides people with the information they need to make a decision to volunteer for a clinical trial). A potential participant should also discuss these with members of the research team and with their usual healthcare provider. Anyone interested in taking part in a clinical trial should know as much as possible about the trial and feel comfortable asking the research team any questions about the trial.

Risks associated with the clinical trial drug

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drug used in this clinical trial. Side effects can be mild to severe and even life-threatening and can vary from person to person.

Giredestrant

Potential participants will be told about the known side effects of giredestrant and where relevant, also potential side effects based on human and laboratory studies or knowledge of similar drugs.

Giredestrant will be given as a pill (to be swallowed). Participants will be told about any known side effects of swallowing pills.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial, but the information that is collected may help other people who have a similar medical condition in the future.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatients page or follow this link to ClinicalTrials.gov https://clinicaltrials.gov/ct2/show/NCT05634499