



The Purpose of The Grace Study

The purpose of the Grace Study is to evaluate the effectiveness (benefits) and safety (side effects) of an investigational study medicine, relacorilant, in treating participants with endogenous Cushing syndrome.

Accessibility

If there is not a participating research site available near you but you are willing to travel, please contact the site of your choice for more information. Compensation for time and travel may be available.



Who May Qualify?

Participants must meet the following criteria*:

- Male or female between the ages of 18 and 80, inclusive
- Diagnosed with endogenous Cushing syndrome
- Willing and able to comply with the study instructions

*There are additional eligibility requirements that the study doctor can explain to you.





If you or someone you know may be interested in participating in the Grace Study, contact a research site via the link below.

[View All Participating Sites](#)

STUDY DESIGN

After an initial screening, the study is divided into two parts.

All study participants will be included in Part 1 of the study and receive study medicine for 6 months. Participants who respond to study treatment will continue to receive study medication or placebo for the last 3 months. Participation in the study could last up to 9 months and include up to 13 visits to the research site. A long-term extension of the study is available to qualifying participants after the completion of Part 2.

SCREENING	 <p>After you consent to participate in the study, you will need to attend a screening visit where your study doctor will perform tests and procedures to confirm your eligibility to take part in the study. The screening portion of the study may last up to six weeks.</p>
STUDY DETAILS	<p> If you qualify based off of the study criteria, you will receive the investigational study medicine. Participants will start on a low dose and the dose will gradually increase over the course of 6 months. You will participate in this part of the study for up to 6 months and will need to visit the research site approximately 10 times. Those who qualify will receive the study medication, study-related medical exams, and study-related laboratory tests at no cost.</p> <p> If you respond to the treatment, you will have a 50/50 chance of continuing to receive the investigational study medicine or receive the placebo. You will remain in the study for an additional 3 months and need to visit the research site approximately three more times. Deterioration of symptoms may happen and rescue criteria is in place to manage this.</p>
LONG-TERM EXTENSION STUDY	 <p>If you complete the study, you will have the option to continue receiving treatment in the long-term extension study. Participants will be on active treatment only; no placebo will be administered. You will be asked to return to the research site periodically for visits to evaluate and monitor you while on treatment.</p>

Common Questions

Will everyone in the study receive the investigational study medicine?

Yes.
If you qualify for and enroll in the study, you will receive relacorilant, the investigational study medicine, for up to 6 months, as detailed in Part 1 of the study design. Then, if you respond to treatment, there is a 50/50 chance that you will either continue to receive relacorilant or be assigned the placebo (inactive medication) over a 3 month period.

Will I have to pay to participate?

No.
Those who qualify will receive the investigational study medicine, study-related medical exams, and study-related laboratory tests at no cost.

Can I leave the study if I change my mind?

Yes.
Participation in any clinical research study is completely voluntary, and you may choose to leave the study at any time for any reason. If you would like to leave the study, you should discuss this with your study doctor, who will give you information about how to do this safely.



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To learn more about the

grace
STUDY

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For additional information, please visit:

[Clinical Trials.gov](https://clinicaltrials.gov)