Will my privacy be protected?

This study will be performed by collecting and using your medical information. Only a number will be used to identify you in the study records. You will not be personally identified or mentioned in any reports or publications that may result from this study. Your personal data will not be used for any direct marketing purposes. Your study records will be kept as confidential as possible and to the extent permitted by the applicable laws and/or regulations.

Who can participate in the REPLACE-CV Study?

You are being asked to participate because you have been diagnosed with advanced prostate cancer, and:

- You are age 18 or older
- You have a history of cardiovascular events or cardiovascular risk factors
- Your doctor thinks you are a candidate for ADT treatment using either relugolix or leuprolide

If you have questions about relugolix or leuprolide acetate or the study, please talk to your doctor.

Dr. Nilay Gandhi (PI)

REPLACE-CV Doctor's Name:

Jessica Vegerano

REPLACE-CV Coordinator's Name:

703.680.2111

Office Phone Number:

REPLACE CV

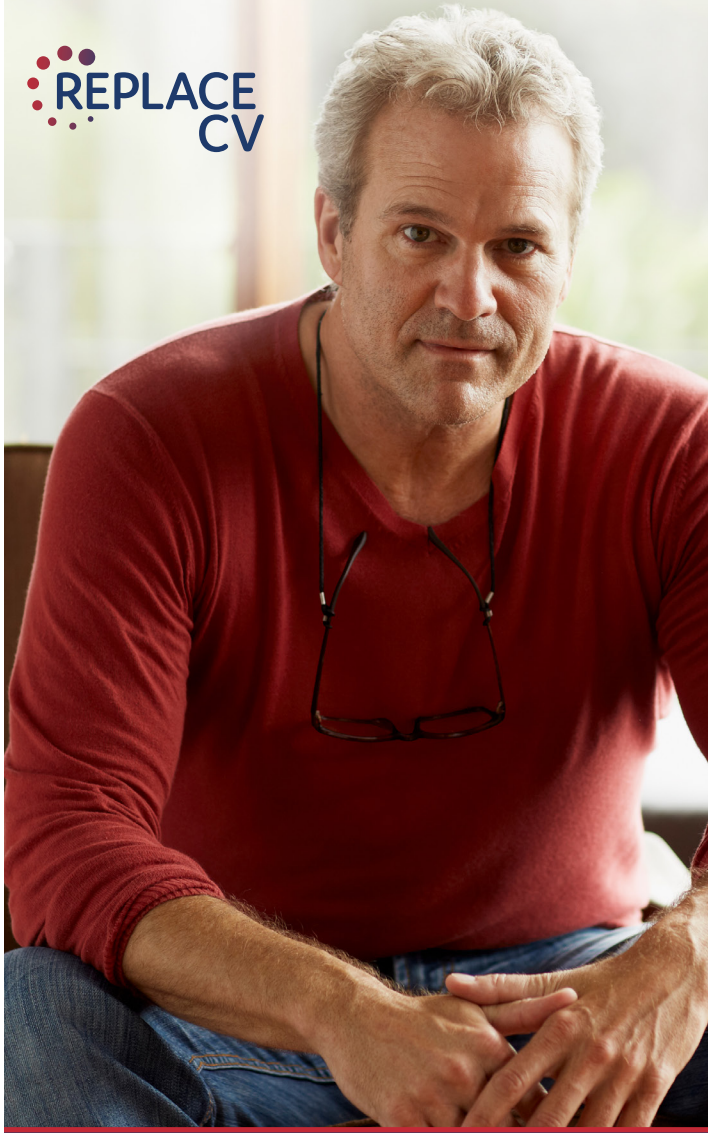
For more information visit

www.clinicaltrials.gov

NCT05605964

A Randomized, Open-Label Study to Assess Major Adverse Cardiovascular Events in patients with Advanced Prostate Cancer

REPLACE CV



Patient Information Brochure

Approved by Sterling IRB, IRB ID: 10366

What is the REPLACE-CV Study?

REPLACE-CV is a study that is evaluating treatments for prostate cancer in patients who also have an increased risk for cardiovascular events. The purpose of this research study is to compare the risk of cardiovascular events between relugolix or leuprolide acetate in patients with prostate cancer. This study is being sponsored by Myovant Sciences GmbH (also referred to throughout this document as "Sponsor" or "Myovant").

Testosterone, a male sex steroid hormone, is needed by most prostate cancer tumors to grow. Treatment with drugs that lower the levels of testosterone in your body is called androgen deprivation therapy (ADT). Both relugolix and leuprolide acetate are used in ADT for patients with advanced prostate cancer.

Why should I participate in the REPLACE-CV Study?

This research is comparing the risk of cardiovascular events between patients who take relugolix or leuprolide acetate for androgen depreviation therapy (ADT), in the treatment of advanced prostate cancer.

Relugolix 120 mg (ORGOVYX®) has been approved by the United States Food and Drug Administration (FDA) for the treatment of adult patients with advanced prostate cancer. Relugolix is a gonadotropin-releasing hormone receptor antagonist and works by lowering the levels of testosterone in your body.

Leuprolide acetate (brand name: ELIGARD® or Lupron®) is an FDA approved medicine that is used most often for androgen deprivation therapy (ADT).

By participating, you may provide new safety and other medical information that may benefit other patients in the future.

How do I enroll in this study?

To learn more about the REPLACE-CV Study and to find out if you qualify for the study, talk to your doctor or their staff.

If you are eligible and would like to participate, you will be asked to provide informed consent to acknowledge your understanding of the study and to provide your consent/permission for the study procedures and for your personal and medical information to be collected. After consent is received, a study representative will contact your doctor to confirm your personal health information.

What is an Informed Consent Form (ICF)?

This form will give you more information about the study and will provide details about the study procedures, when the study procedures will occur, and what will be required of you as a study participant. This informed consent form describes the known risks and possible benefits of participating in this study. The form also explains how your medical information from the study will be used and who may see it.

You will be given a copy of this informed consent form to review on your own or to ask advice from others. Ask your study doctor or study staff to explain any words or information you do not understand. You should not sign this form if you have any questions that have not been answered.

What will my participation involve once I am enrolled?

This study includes a screening period of up to 14 days in which your study doctor will determine if you meet all the requirements for study participation. You may be reimbursed for reasonable travel expenses to the clinic during this period, and for every questionnaire you complete, receiving up to $150.00 for every year that you participate in the study.

If you are eligible for and willing to participate in the study, you (or your caregiver) will be asked to complete questionnaires electronically (such as computer, tablet, or smartphone) and/or share information via phone calls every three months until the end of your participation in the study. There is no fixed or preset length of time for you to be followed in the study.

As part of the study, you will see your study doctor either in the clinic or by telehealth visit once every three months, and you will receive routine medical care (such as laboratory tests including testosterone and prostate specific antigen [PSA] levels).

In addition, you will receive the study medication for treatment (either relugolix or leuprolide acetate) at no cost to you, and Myovant will continue to cover the costs of study treatment (either relugolix or leuprolide acetate) for as long as you participate in the study. Taking part in this study is voluntary. If you sign up and later decide that you do not want to continue, you can stop at any time.

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