About Genetic Dilated Cardiomyopathy

Dilated cardiomyopathy (DCM) affects the heart's ability to pump blood efficiently. The disease often starts in the heart's main pumping chamber: the left ventricle. The heart muscle begins to dilate, stretching and becoming thinner. As a result, the left ventricle becomes enlarged and the problem often spreads to the remaining chambers of the heart.

As the heart chambers dilate and enlarge, the heart muscle doesn't contract normally and cannot pump blood very well. As the heart becomes weaker heart failure can occur. Common symptoms of heart failure include shortness of breath, fatigue and swelling of the ankles, feet, legs, abdomen and veins in the neck. DCM also can lead to heart valve problems, arrhythmias (irregular heartbeats) and blood clots in the heart. DCM can be silent for many years until symptoms occur.

Often times the cause of DCM is unknown, referred to as idiopathic DCM. However, there is growing evidence that most idiopathic DCM is genetic and can run in families. Genetics is the study of genes, genetic variation, and heredity in living organisms. This study is evaluating how effective a study medication is for treating adults with dilated cardiomyopathy (DCM) due to a genetic mutation called Lamin A/C (LMNA).

Contact a Study Team Member to Learn More

If you have questions about this study, please reach out to the study team. Don't have questions now? You can always call or email the study team later.

Clinic Name: _____

Contact Person: _____

Address: _____

Telephone Number: _____

Email Address: _____

PFIZER-ARRAY-C4411002_BROCHURE_V1.2_UK-EN_28JUL2021

LMNA-RELATED DCM STUDY

Together, we can take on genetic dilated cardiomyopathy.

Consider joining a clinical research study that will look at how effective a study medication is for treating LMNA-related dilated cardiomyopathy (DCM) in adults.

REALM-DCM

About This Study

The REALM-DCM study is being conducted to see if a study medication (compared to a placebo) can safely improve a participant's physical capacity and quality of life. This is a two-part study: Part 1 is made up of a randomised and blinded period while Part 2 is made up of an open-label period.

A computer will randomly assign participants to receive either the study medication or placebo during Part 1. Neither participants nor the study doctor will know which individuals are receiving the study medication or a placebo. One half of the study participants will receive the study medication, and the other half will receive the placebo (capsule with no active ingredient). Participants who are given the placebo during Part 1 of the study will have the opportunity to receive the study medication during Part 2 (open-label) of the study.

Why Should I Participate?

If this study is right for you, you will receive study-related care and the study medication at no cost.

Study-related doctor visits will provide you with thorough exams and your care will be carefully monitored throughout the study. Your study medication will be provided throughout the research study. Plus, you may be reimbursed by the study site to cover reasonable expenses (for example, parking, meals, travel) that you have as a result of taking part in this study.

Your time is valuable, and we appreciate your interest in advancing LMNA-related DCM research.

What To Expect

Before you begin the study, you will have medical tests and procedures to help the study doctor decide if you can participate. If this "screening" phase determines the study is right for you, you will return to the study site for a baseline visit.

After the baseline visit, you will return to the study clinic at weeks 4, 8, 12 and 24, and then every 12 weeks until the end of the study. At some clinic visits (including the screening and baseline visits) you will be asked to complete a test to see how far you can walk in 6 minutes. Additionally, the study doctor will review your medical history, give you a physical exam and conduct some tests, including taking blood and urine samples. Participation in the study will last at least 24 weeks (6 months).

About Clinical Research

Without clinical trials, most common medications that people use every day would not be available. Before a medication can be approved for use by patients, a thorough process of research must be conducted. This includes testing a study medication in clinical trials involving people.

Clinical research studies are essential to understanding more about genetic DCM and developing medicines which may provide potential treatments for patients.

All clinical trials are designed with the safety of the study participants in mind. The team of medical professionals running the trial oversee the health of study participants throughout the trial.

This study is in addition to your regular medical care. Choosing to take part in a clinical research study is an important and voluntary decision. Please take time to think about the information shared with you and remember that expressing interest or asking questions does not mean you have to take part.

How Do I Participate?

If you are interested in taking part in this clinical research study or would like more information, please speak with your doctor during your regular appointment or contact a member of the study staff using the details on the back cover of this brochure.

Can I Participate?

You may meet eligibility criteria to take part in this clinical study if you:

- Are at least 18 years old
- Have an implantable cardioverter defibrillator (ICD) or cardiac resynchronisation therapy defibrillator (CRT-D). The device must include pacing capabilities, or a separate pacemaker must be present.
- Have symptomatic LMNA-related DCM

Note: These are not the only eligibility criteria for this clinical research study, and other criteria may exclude you. A clinical research team member will help determine if you meet eligibility criteria to participate.