Ahmanson/UCLA Adult Congenital Heart Disease Center

Dedicated to the Future of Children

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Website: www.heart.ucla.edu/achdc

Date: 1 1/14/2022

RE: A Randomized Trial of Closed Loop Stimulation after Pacemaker Implantation for
Congenital heart Disease
NCT: NCT03361 189
Protocol ID: 17-000932
Date: 1/11/2017

Please find attached Consents from 7/23/2018 to 3/10/2021.

Sincerely,

Jeremy P. Moore, MD, MS, CCDS, CEPS, FHRS

Fellowship Program Director I Director of Clinical Research I Division of Pediatric Cardiology
Clinical Faculty I Ahmanson-UCLA, Adult Congenital Heart Disease Program
100 Medical Plaza Drive, Suite 770
Los Angeles, CA 90095

UNIVERSITY OF CALIFORNIA LOS ANGELES CONSENT TO PARTICIPATE IN RESEARCH

A Randomized Trial of Closed Loop Stimulation after Epicardial Pacemaker Implantation for Congenital Heart Disease

INTRODUCTION

Jeremy P. Moore, MD MS, and associates from the Pediatric and Adult Congenital Heart Disease Program at the University of California, Los Angeles are conducting a research study.

The researchers will explain this study to you. Research studies are voluntary and include only people who choose to take part. Please take your time about deciding whether to participate in this study. Before deciding:

- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion. • If you have any questions, you can ask the researchers for more information before deciding to participate.

The research team is asking you to be in this study because you have been identified as having congenital heart disease with a surgical pacemaker for sinus node dysfunction.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to determine if a new type of pacing is helpful in terms of quality of life and exercise tolerance after cardiac surgery.

Your pacemaker company (Biotronik Inc.) has included the software for the unique pacing algorithm in all of its cardiac implantable electronic devices (i.e. pacemakers and defibrillators). The pacing algorithm is approved by the FDA, but has not been studied specifically in patients with various forms of congenital heart disease. This study is sponsored financially by Biotronik Inc.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

Before you begin the study:

Before you begin the study, you will need to review this consent form carefully and decide if you are willing to participate. If you decide to participate in the study, you must sign your name and return this form to the study investigators.

During the study:

If you take part in this study, you will be randomly assigned to one of two possible pacemaker modes. The first pacing mode is your current pacing mode, which is based on a type of motion sensor (also known as an "accelerometer") to determine your target heart rate. The second pacing mode ("closed loop stimulation" or "CLS") relies on the pacemaker's determination of the force of contraction of your heart to estimate your target heart rate. Both pacemaker modes are FDA approved for regulation of heart rate. The second pacing mode, or "CLS" has not been studied in patients with congenital heart disease however.

At the end of 3 months, the researchers will ask you to complete a questionnaire describing your quality of life as well as perform a series of cardiac tests that include activities while wearing a gas exchange mouthpiece, testing of your autonomic nervous system function, and a mental stress test. Autonomic function testing involves testing of the unconscious part of your nervous system that is responsible for automatic activities such as regulation of heart rate, respiratory rate, digestion, and sweating, etc. This testing involves measures of blood pressure, heart rate, and sweating response to activities such as standing, deep breathing, forced exhalation (also known as a "Valsalva maneuver"). The mental stress involves completion of moderately complex mathematic problems, in order to assess your heart rate response during this type of challenge.

The time required for these activities is generally 10 minutes or less for the quality of life questionnaire, 20 minutes for exercise testing, and 30 minutes for the combination of autonomic function testing and mental stress testing (the total testing time is expected to last approximately 1 hour).

You will then be placed in the alternate pacing mode for an additional 3 months, after which all of the tests will be repeated. At the conclusion of the study, the pacing mode that is most helpful for you will be revealed, and your pacemaker will be programmed to that particular pacing mode.

HOW LONG WILL BE IN THIS STUDY?

This study will last 6 months.

WHAT KINDS OF RISKS OR DISCOMFORTS COULD I EXPECT?

Known risks and discomforts:

The possible risks and/or discomforts associated with the procedures described in this consent form include:

There are risks associated with exercise in patients with congenital heart disease, including the risk of provoking ventricular arrhythmia. Nevertheless, exercise testing (including gas exchange monitoring) is routinely performed as a part of the routine evaluation process and will not differ from standard testing in this study.

There is a risk of inappropriately fast pacing associated with the CLS algorithm. The degree of excessively fast pacing is limited by the study investigator at the time of pacemaker reprogramming however, so that should this occur, symptoms are expected to be limited to the sensation of palpitations. The pacemaker will not be permitted to pace your heart at dangerously fast levels on the basis of this programming.

Unknown risks and discomforts:

The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

Possible benefits to me:

The possible benefits you may experience from being in this study include a greater understanding of how your heart responds to different pacemaker modes. This information may be useful for future management of your cardiac pacemaker.

Possible benefits to others or society:

This study will help the researchers learn more about cardiac pacemakers after surgery for congenital heart disease. Hopefully this information will help in the treatment of future patients with sinus node dysfunction like yours.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

This study will involve approximately 12 patients over the course of 5 years. Atl of the participants will have similar forms of congenital heart disease and requirements for pacemaker placement.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

If you decide not to take part in this study, or if you withdraw from this study before it is completed, you will continue with your current pacemaker programming and future changes will only be made as deemed necessary by your cardiac care provider.

CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY?

The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled visits. The researchers or the study sponsor might also decide to stop the study at any time.

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How long information from the study will be kept:

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CONSENT

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