RESPONDER-HF Clinical Study

HAS HEART FAILURE LEFT YOU BREATHLESS?

Relief may be possible with the Corvia® Atrial Shunt

corvia®

Heart failure can be life-altering. Between the discomfort of symptoms and the feeling of missing out on everyday things, it's a condition that can leave you breathless.

Fortunately, a sigh of relief is possible.

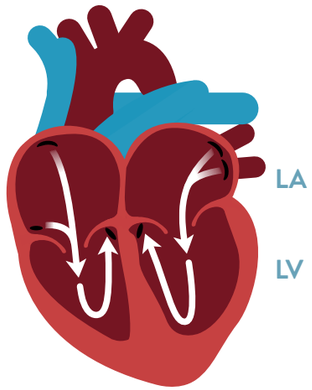
The Corvia® Atrial Shunt is an investigational device designed to relieve the breathlessness, fatigue, and hospitalizations caused by a kind of heart failure called HFpEF. A small cardiac device implanted by a cardiologist, the Corvia Atrial Shunt decreases pressure in the left side of the heart and lungs to reduce heart failure symptoms. Implanted in more than 550 patients in 18 countries, it's also the most widely studied atrial shunt in heart failure.

The effectiveness of the Corvia Atrial Shunt is being evaluated in a clinical study called **RESPONDER-HF**. If you're over age 40, living with HFpEF, and medications haven't made you feel better, you may qualify to take part in the RESPONDER-HF study.

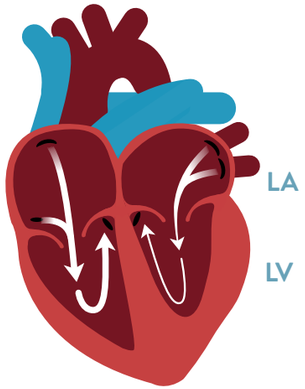
Read on to find out if this study may be right for you.

UNDERSTANDING HEART FAILURE

Heart failure (HF) is a condition in which a heart is unable to pump sufficiently, or does so at higher filling pressures, to meet the needs of the body. One of the common symptoms is build-up of fluid in tissues and veins, causing water retention, swelling and breathlessness.



In a **healthy heart**, the left ventricle (LV) and left atrium (LA) relax to fill with blood from the lungs. Once filled, the left ventricle pumps the blood to the body.



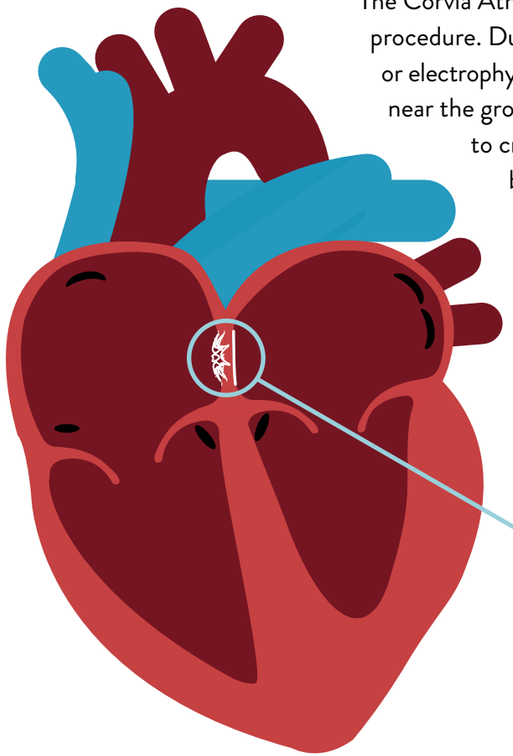
Heart failure with preserved ejection fraction (HFpEF) occurs when the muscles of the left atrium (LA) and ventricle (LV) become stiffer and are unable to relax normally. As a result, blood cannot easily enter the LA or LV with each heartbeat, causing high pressure inside the lungs and left heart chambers.

The high pressure in the lungs and left side of the heart causes shortness of breath and fatigue. These are common symptoms of worsening heart failure and can make daily activities challenging and even result in hospitalization.

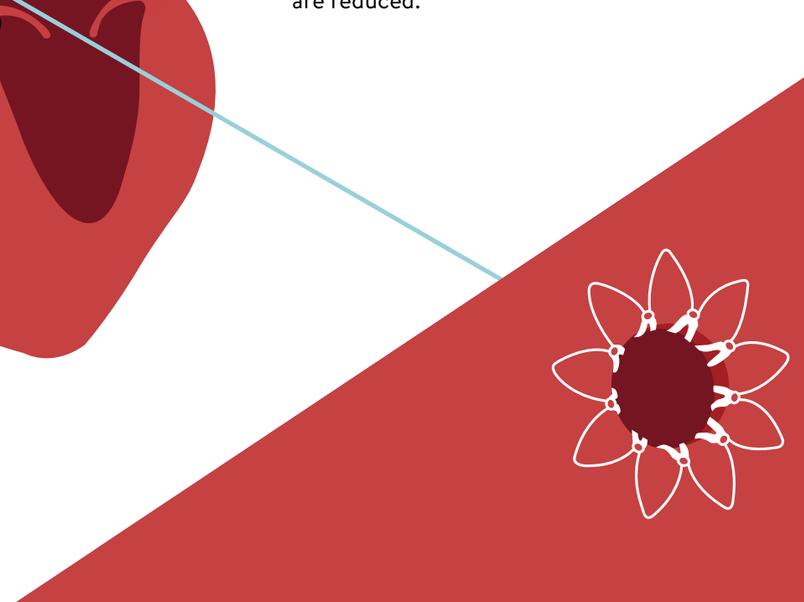
Ejection fraction = the percentage of blood that leaves the left ventricle with each heartbeat

HOW THE CORVIA ATRIAL SHUNT WORKS

The Corvia Atrial Shunt is an investigational cardiac implant designed to reduce heart failure symptoms by decreasing pressure in the left side of the heart and lungs.



The Corvia Atrial Shunt is implanted via a minimally invasive procedure. During this procedure, an interventional cardiologist or electrophysiologist inserts a catheter (small tube) in a vein near the groin to access the heart. This catheter is then used to create a very small passage in the heart wall between the right and left atria where the shunt is placed. The newly created passage allows blood to flow from the high pressure left atrium to the lower pressure right atrium. As a result, the pressure in the left side of the heart and the lungs decreases, and heart failure symptoms are reduced.



THE RESPONDER-HF CLINICAL STUDY

The effectiveness of the Corvia Atrial Shunt is being confirmed through an FDA approved clinical study called RESPONDER-HF.

If you are 40 years of age or older, experience heart failure symptoms despite medication, and meet additional criteria, you may be eligible to receive the Corvia Atrial Shunt by participating in the study.

To best confirm the device's effectiveness, RESPONDER-HF is a randomized study. This means that half of study participants will receive a device, and half will not. Participants will be informed about whether they received a device 2 years after the procedure. At that time, participants who did not receive a device may have the opportunity to receive one.

Participating in RESPONDER-HF will provide you potential access to a device not yet available to the wider public. In addition, regardless of whether or not you receive the device, you will be seen frequently and receive the best care possible.

BENEFITS AND RISKS

As with any medical procedure, the Corvia Atrial Shunt has potential benefits and risks. It is important that you talk with your doctor to understand the benefits and risks associated with this device.

Potential benefits for people implanted with the Corvia Atrial Shunt as part of this study include the following:

- Less shortness of breath
- Fewer HF hospitalizations and/or days in the hospital for HF symptoms
- Fewer emergency room visits
- Reduction in heart failure medications
- Improved exercise tolerance
- Better quality of life

The risks associated with the implant procedure are similar to the risks of other catheter based cardiac procedures in which devices are permanently implanted in the atrium or in the heart wall between the two atria. Because these procedures are routine, these potential risks are uncommon; interventional cardiologists, electrophysiologists and their staff are well trained to reduce the likelihood and manage procedural risks.

Potential but uncommon long-term device risks include movement or fracture after placement, a blood clot that forms on or near the device and travels through the heart causing a blockage of a blood vessel (embolization, infarction with potential stroke), perforation or erosion of the heart wall, headache, chest pain, heart rhythm changes, or gradual implant occlusion and return of HF symptoms. The device is intended as a permanent implant, and does not need to be removed unless there is a medical reason to do so.

WHAT TO EXPECT AFTER THE PROCEDURE

After the procedure, you will spend the night in the hospital and go home the next day.

Short-term medication will be prescribed, unless you are already on a blood thinner. Remain diligent with all prescribed heart failure and other medications.

You will be given an implant identification card containing information about the study. Keep this card with you and show it to any healthcare providers that treat you in the future.

Once at home, it is important that you avoid strenuous physical activity for at least 2 weeks.

Seek immediate medical attention if you experience a sudden increase in heart failure symptom frequency or severity.

AM I ELIGIBLE FOR THE RESPONDER-HF STUDY?

If you are 40 years or older, suffer from heart failure symptoms despite taking medication, and meet study criteria, you may be eligible to participate.

For more information, talk to your doctor or visit: treatmyheartfailure.com

Study sponsored by Corvia Medical. clinicaltrials.gov identification #NCT05425459

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The Corvia Atrial Shunt System is an **Investigational Device,** exclusively for use in a Clinical Investigation.