Frequently Asked Questions

What is this study?

This is a clinical trial to evaluate how a personalized pacing rate will impact patients diagnosed with Heart Failure with preserved Ejection Fraction (HFpEF).

Who is eligible?

You may be eligible if you fit all the of the following:

- Have a diagnosis of heart failure
- Have had a recent hospitalization or emergency room visit for worsening heart failure symptoms
- Do not currently have a pacemaker or similar device

How long will it take?

Your participation may last up to 4.5 years, depending on when you are enrolled.

How many people will be involved?

An estimated 700 patients will be enrolled at up to 75 locations worldwide.

How much will it cost?

Testing and services done for the study will be provided at **no cost to you** and will not be billed to your insurer.*

*You or your health insurer will be responsible for all costs that are part of your normal medical care. If your health insurer requires a co-payment, co-insurance, or deductible, you will be responsible for making that payment.

Learn more about this trial

Scan the QR code to visit **clinicaltrials.gov**

Medtronic

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Notice of Availability for a clinical study investigating a new indication for a pacemaker in patients with Heart Failure with preserved Ejection Fraction (HFpEF).

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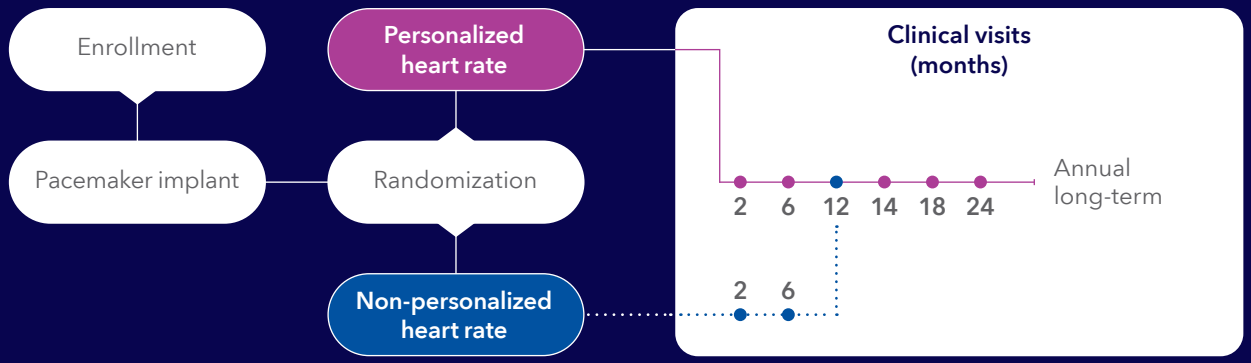
ELEVATE-HFpEF clinical trial

Have you been diagnosed with Heart Failure?

A new research trial is being conducted to determine if pacing your heart at a rate personalized to your heart measurements and your height can improve Heart Failure symptoms.

What is going to happen during the study?



Enrollment

After verifying your eligibility, the study team will gather baseline information so they can check for changes later in the study. This will involve:

- Full medical history
- Medication information
- Health status questionnaire
- Echocardiogram
- Blood draw for lab work
- 6-minute walk test
- 24-hour wearable monitor

Pacemaker implant

This is a small medical device that is implanted under your skin. It continuously monitors your heart through wires that carry electrical signals to and from your heart. For patients whose heart beats too slowly, pacemakers can send signals to the heart to speed up the heart rate.

It's currently unknown if setting heart rates with pacemakers helps with HFpEF. If you decide to participate in this study, you will have a Medtronic pacemaker implanted by your doctor.

Learn more about pacemakers

Visit **Medtronic.com** and select:

Patients & Caregivers >
Treatments & Therapies >
Heart & Vascular

Randomization

Once you have your pacemaker implanted, you will be randomly assigned to a trial group. **You will not know which group you are in during the trial.**

Personalized heart rate
One group will have their hearts paced at a personalized rate based on height and measurements from their echocardiogram

Non-personalized heart rate
The other group will have their pacemaker set at a non-personalized rate which will pace their heart when their heart rate drops below the standard rate

After 12 months, all participants will move to the personalized group

Clinical visits

In this study, the study staff will schedule **at least 6 visits** with you. **It is important that you make every effort to attend your scheduled appointments.** Some of your visits may be done remotely if you are enrolled in MyCareLink.

During these visits, your doctor and the research team will ask questions and check your pacemaker. They may also take your blood pressure, do a blood draw or repeat the 6-minute walk test. Some visits will require an echocardiogram and an electrocardiogram.

What are the benefits?

Possible benefits include:

- Improvement in health status
- Increased monitoring
- Increased level of physical activity
- Preservation or improvement in quality of life
- Reduced atrial fibrillation (irregular heartbeat)
- Reduced number of heart failure hospitalizations

There may be no direct medical benefit.
The information from this study may benefit other people with HFpEF in the future.

Are there any risks?

This study has been designed to involve as little pain, discomfort, fear and other foreseeable risks as possible. Risks will be continuously monitored, assessed and documented.

Possible risks include:

- Risks associated with implantation surgery and use of pacemakers and pacing leads, such as:
  - Allergic reaction or device rejection
  - Tissue, vascular, and valve trauma
  - Skin erosion
  - Pain or scarring
- Radiation exposure from X-ray procedures and fluoroscopy evaluation
- The personalized cardiac pacing may be less effective than your current medical care

There may be additional risks not yet known.

If you are interested and your doctor determines you are eligible to participate, you will be given a consent form that will contain a more detailed description of the study including additional possible risks of the device and study participation.