

# Medtronic

## ELEVATE-HFpEF clinical study

Hospital name

Primary investigator name

Research coordinator name

Questions (name/phone number)

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



### What is the study about?

In patients with HFpEF, the study will evaluate if pacing therapy influences patient outcomes, such as improved quality of life and fewer visits to the doctor and hospital.



### How long will it take?

At least 18 months and up to 54 months.



### Can I leave the study early?

You can withdraw from the study at any time.

### Study timeline

Enrollment

Pacemaker implant/procedure

Randomization

Personalized heart rate

Non-personalized heart rate

### Check-in visits

2 months

6 months

12 months

14 months

18 months

24 months

Annual long-term

End of study

### What will happen when I start the study?

After verifying your eligibility, we will gather baseline information from you – this gives us an idea of how you are doing so we can see any changes later. This includes:

- Full medical history
- Physical exam
- Medication information
- Echocardiogram
- Blood draw for lab work
- 24-hour wearable monitor
- 6-minute walk test
- Blood pressure

### What does the therapy do?

Your doctor believes that using a pacemaker to personalize your heart rate may have a positive clinical impact on your health, including your overall quality of life. This is what is being investigated in the clinical study.

### Which group will I be in?

To make sure the data collected from you is not biased, you will not know which group you are assigned until the 18 month visit.

**All patients will have their pacemaker programmed to the personalized cardiac pacing rate at their 12 month visit.**

### Which tests will I need during the study?

During the check-in visits, we may perform some procedures to see how the treatment is working. These include but are not limited to:

- Echocardiograms
- 24-hour wearable monitor
- Questionnaires (KCCQ, EQ-5D-5L)
- 6-minute walk test
- 12-lead ECG
- Blood draw
- Device check

