

# Brooklyn Enrolls One of First Participants in a Female-Only Study of Coronary Interventions



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**Ashley Gutierrez, clinical research coordinator at NYU Langone Hospital—Brooklyn, explains her work enrolling women in the Empower CAD study, and details the passion she brings to recruiting Brooklynites for other clinical trials.**

*For many years, women battling coronary artery disease (CAD) have had poorer outcomes than men, and little research has focused on explaining this disparity—until now. The Empower CAD clinical trial—run by the Shockwave medical device company and led by two US coronary intervention experts and one in Spain—launched in May 2023 and has enrolled 310 of its goal of 400 female patients from the United States and Europe. The study aims to understand why women don't do as well with treatments for CAD, which occurs when arteries supplying blood to the heart narrow due to calcium buildup, leading to possible heart attacks. Ashley Gutierrez, clinical research coordinator at NYU Langone Hospital—Brooklyn, talks about Brooklyn's role in the study.*

## **Women are under-researched in clinical studies. How will Empower CAD counter that?**

A lot of clinical research is geared toward studying men. But women often have different risk factors and disease progression than men, so gender-specific research is essential. We can't make advancements in women's health without studying women, right? NYU Langone Health is among the top 10 enrollers (out of 50 sites) of participants in the Empower CAD study, which tracks women battling CAD over a three-year period. I'm proud to say the first patient NYU recruited for the study came from Brooklyn. She's an 84-

year-old who had a mild heart attack. After she stabilized, I was able to enroll her in the program. She told me she admired its mission.

### How does the study work, and what do leaders hope to learn from the data?

While participants are in the study, they receive treatments for their CAD. That involves shockwave treatment—called Intravascular Lithotripsy (IVL)—that applies pressure waves to break up calcified plaque in the arteries prior to placing a stent to keep the blockage open. While they're in the program, we evaluate the women regularly, gathering updates on their health, medications, and quality of life. With that data, the hope is to develop best practices for managing CAD among women, and how gender-specific factors influence treatment outcomes like heart attacks and strokes.

### Besides Empower CAD, you've had a lot of success enrolling patients in clinical trials since NYU Langone started a research program in the borough less than two years ago. Can you share some highlights?

We enrolled our first patient in a trial in November 2022 and we didn't stop. Our first study, PROLOCOR, aimed to find out if levels of a protein on platelets are linked to the risk of heart attacks or strokes. We enrolled 51 Brooklyn patients. As I'm the only cardiology catheterization lab coordinator at NYU Langone Hospital—Brooklyn, it's been a passion project of mine to find as many Brooklyn patients as possible for our studies. Currently, we're enrolling patients in six different trials. In total, we now have 148 Brooklyn patients enrolled across our studies.

### You've also worked to get a more diverse mix of Brooklynites into our trials. Tell us more.

I've lived in Brooklyn my whole life, and it's great to have Brooklyn patients with all kinds of backgrounds represented. Sometimes that means getting an interpreter or forms available in different languages. For instance, we're recruiting in English, Spanish, Polish, Arabic, Chinese, and Russian for the IMPROVE study, which looks at the impact of a procedure called intravascular ultrasound (IVUS) that uses sound waves to evaluate coronary lesions for appropriate stent sizing. Until we started recruiting here, Brooklyn patients were not often considered for trials. But now our whole population can be screened and assessed. Some patients will say, "I never thought anyone would ask me to be in a clinical study. This is cool."

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