

UW Health: Treats first patient in the country with investigational cell therapy for heart disease

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MADISON, Wis. — Appleton resident Donald Krause became the first patient in the country last week to undergo an investigational cell therapy for a debilitating heart condition called chronic myocardial ischemia (CMI).

Krause, who's been suffering from CMI for years, volunteered to be part of the Phase III CardiAMP Cell Therapy Trial at University Hospital after all other established therapies failed to resolve his symptoms.

Myocardial ischemia occurs when blood flow to the heart is reduced, preventing the heart muscle from receiving enough oxygen. The reduced blood flow is usually the result of a partial or complete blockage of the heart's arteries (coronary arteries). Patients with CMI have frequent chest pain (angina) that is not controlled well by drug therapy and they are not considered suitable candidates for stent placement or bypass surgery, leaving them with limited therapeutic options. It is estimated that between 600,000 and 1.8 million patients in the U.S. suffer from treatment-resistant myocardial ischemia, with approximately 75,000 new cases diagnosed each year.

Krause was treated with the investigational CardiAMP cell therapy by Dr. Amish Raval, interventional cardiologist at UW Health and associate professor of medicine at the UW School of Medicine and Public Health, and supported by Dr. Peiman Hematti, bone marrow transplantation hematologist and professor of medicine at SMPH.

"Our hope is that the addition of CardiAMP cell therapy to the best therapeutic options currently available for CMI will help improve the quality of life for patients like Mr. Krause and the tens of thousands of other people who are diagnosed each year," said Raval, who is also the primary investigator for the trial at UW Health.

“Patients with CMI are often desperate to find relief after suffering for years with debilitating symptoms, and this therapy, if proven successful during this trial, could become not only the first cell therapy of its kind for heart disease but a real gamechanger for these patients in particular.”

CardiAMP Cell Therapy uses a patient’s own (autologous) bone marrow cells delivered to the heart in a minimally invasive, catheter-based procedure to potentially stimulate the body’s natural healing response. The technique incorporates a unique pre-procedural screening assay to identify those patients who are likely responders to the intervention, a first for a cardiac cell therapy. Patients in the trial are typically treated and discharged from the hospital the morning after the study procedure.

For Donald Krause, a renowned French horn player and musical conductor, the benefits of volunteering for this clinical trial are twofold: the opportunity to contribute to science in a way that could potentially help others suffering from heart disease; and a hope that such an intervention might keep him playing his French horn for many more years to come.

“I’m 81 years old now, but I’d like to play my French horn until I’m at least 91, and maybe even 101,” said Krause. “Music is obviously very important to me, but so is good health. I’ve seen a lot of people die from heart disease over the years, and I hope that my participation in this trial today might help many thousands of people in the future.”

The CardiAMP Cell Therapy Chronic Myocardial Ischemia Trial is expected to enroll up to 343 patients at up to 40 centers nationwide.

Raval also serves as a national co-principal investigator for the ongoing CardiAMP Cell Therapy for Heart Failure trial that paved the way for the new chronic myocardial ischemia trial. Earlier this year, the FDA approved a detailed protocol amendment to shorten the CMI trial’s primary endpoint to a six-month follow-up from one year, and to harmonize details of the protocol to correspond with the actively enrolling CardiAMP Cell Therapy Heart Failure Trial, which has incorporated best practices from significant interactions with study centers and the FDA. More information about the trial is available at uwhealth.org/cardiAMPtrial.