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# Researchers lead first worldwide trial to test defibrillators in diabetes patients

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Individuals with diabetes have a high incidence of heart problems, including sudden cardiac death. A study led by researchers at the University of Rochester Medical Center (URMC) will determine if a subcutaneous implantable cardiac defibrillator (S-ICD) increases survival in this growing group of patients.

The global clinical trial will enroll individuals with diabetes who are 65 years and older, have had a heart attack and have slightly reduced heart function, as measured by the heart's ability to pump blood throughout the body. Study leader Valentina Kutyifa, M.D., Ph.D., research assistant professor of Cardiology at URMC's Heart Research Follow-up Program says all of these factors greatly increase the risk of sudden cardiac death, yet these patients are not considered candidates for defibrillators under existing medical guidelines.

"We think that this is an untouched population of patients who could really benefit from the device," said Arthur J. Moss, M.D., professor of Cardiology at URMC who is one of the world's foremost experts on the use of defibrillators.

Defibrillators detect and correct irregular heart rhythms that, if left unchecked, could lead to sudden cardiac arrest and death. The S-ICD – the newest type of ICD device – is less invasive than a traditional ICD; it is implanted just under the skin and does not require leads or wires to be connected to the heart. It uses a special sensing technology to detect dangerous heart rhythms without touching the heart and surrounding

vessels.

"This study is important because we need new, improved ways to mitigate sudden death in people with diabetes," said Stephen R. Hammes, M.D., Ph.D., chief of the division of Endocrinology, Diabetes and Metabolism at URMC who will help enroll participants in the trial. "Patients are often prescribed beta blockers, ACE inhibitors, statins and other drugs to manage heart disease, but a defibrillator could provide an increased level of protection not afforded by medication alone."

Kutyifa adds that eliminating device leads through the use of the S-ICD is critical for patients with diabetes, as they often have compromised immune systems and an increased risk of infection. Leads provide a potential pathway for bacteria to spread to the heart and can cause unnecessary patient complications.

According to the Centers for Disease Control and Prevention and the American Diabetes Association, diabetes affects nearly 29 million people in the United States alone and claims more than 250,000 lives annually. Adults with diabetes are two to four times more likely to die from heart disease than those without.

The Multicenter Automatic Defibrillator Implantation Trial with Subcutaneous Implantable Cardioverter Defibrillator (MADIT S-ICD) study will enroll 1,800 patients at approximately 100 sites in the United States, Europe and Israel to determine if the S-ICD improves survival as compared to patients remaining on their current medical therapy. The trial is sponsored by Boston Scientific, maker of the EMBLEM MRI Subcutaneous Implantable Defibrillator (S-ICD) System.

Interdisciplinary teams of electrophysiologists, cardiologists and endocrinologists – all who care for patients with diabetes – will manage enrollment at each study site. Special effort will be made to enroll a large

number of women, who are consistently underrepresented in clinical trials. A study in *Circulation: Cardiovascular Quality and Outcomes* found that between 2000 and 2007 the average number of women enrolled in U.S. cardiovascular device clinical trials was only one-third of the total study populations.

This is the fifth major defibrillator study led by the University of Rochester; the initial MADIT trial was launched in 1989. These studies have proven the benefits of defibrillators in various groups of patients and changed medical guidelines worldwide to include life-saving ICD therapy.

Provided by University of Rochester Medical Center