Southcoast Health's Charlton Memorial Hospital first in the world to enroll and treat patient in LIFE-BTK PK substudy

Clinical study researches advanced treatment for patients with Critical Limb Ischemia (CLI).

Southcoast Health Chief of Vascular Surgery Dr. Richard Pin and a team at the Heart and Vascular Center at Charlton Memorial Hospital became the first to enroll and treat a patient in the national LIFE-BTK randomized clinical trial PK sub-study, system officials announced today.

"We are honored to be part of this clinical trial," says Dr. Pin. "It is an amazing achievement for a community health system to be asked to participate in a randomized clinical trial, and for Charlton to go above the pace that was expected in enrolling patients is testament to the hospital's exceptional cardiovascular program. This trial serves a need for critical patients in the south coast region who would otherwise have limited options. I am proud of our team for their outstanding work to advance cardiovascular care in our community."



SouthCoast health photo.

The LIFE-BTK trial is designed to evaluate the Esprit™ BTK Drug-eluting Resorbable Scaffold for the treatment of below-the-knee artery stenosis in symptomatic critical limb ischemia (CLI) patients, evaluating it against Percutaneous Transluminal Angioplasty (PTA). Unlike other drug-eluting stents, the Esprit-BTK investigational device is not a permanent implant; it provides support to an artery immediately after a balloon angioplasty, preventing the vessel from reclosing. Once implanted, the scaffold delivers a drug over a few months to promote healing and keep the artery open before dissolving.

CLI is a severe form of Peripheral Arterial Disease (PAD) that can lead to amputation. It involves the narrowing or blockage of the peripheral arteries carrying blood from the heart to the legs and arms and is estimated to affect approximately two million people nationwide. This decreased blood flow to lower limbs and can lead to increased mortality rates and amputations if left untreated.

The PK sub-study takes the clinical trial a step further to evaluate the effectiveness of the drug everolimus by analyzing numerous blood samples taken at predetermined times. This sub-

study is only planning to enroll 7 patients nationally due to the very limited inclusion criteria.

"We are grateful to have had a patient willing to participate considering the number of blood draws that are required both at the hospital and for months thereafter," says Debra Benevides, a Clinical Research Coordinator at Southcoast Health. "In this study, blood samples were collected every 15 minutes during the procedure and then at regular intervals over the next 60 days. Clinical trials are successful because of the patients who are willing to participate and donate their time." The initial procedure was performed on February 10, 2022.

Charlton Memorial's Heart and Vascular Center continues to be a regional leader in advanced cardiovascular services. "I want to congratulate Dr. Pin and his team once again for their outstanding work to provide advanced cardiovascular care to our patients," says Dr. Peter Cohn, Physician in Chief of the Cardiovascular Care Center at Southcoast Health. "Participating in this randomized clinical trial sub-study demonstrates Southcoast Health's commitment to bringing innovative technology and research to patients in our community."

More information about the Heart and Vascular Center at Charlton Memorial Hospital can be found here.

About Southcoast Health

For more than 25 years, Southcoast Health has served communities across southeastern Massachusetts and Rhode Island as the largest provider of primary and specialty care in the region. The not-for-profit, charitable system includes three acute care hospitals — Charlton Memorial in Fall River, St. Luke's in New Bedford (a Level II Trauma Center), and Tobey in Wareham — as well as a network of over 700 physicians, hospitalists, and midlevel practitioners.

Southcoast Health has established seven Urgent Care Centers, two Cancer Centers, a Visiting Nurse Association, and numerous ambulatory facilities that ensure convenient access to services for 725,000 residents in 33 communities covering 900 square miles. In addition, the system partners with Acadia Healthcare to offer expanded resources at Southcoast Behavioral Health in Dartmouth.

Southcoast Health is a Newsweek's World's Best Hospital in 2019, 2020, 2021 and 2022. In 2021, St. Luke's was named to Newsweek and Leapfrog's Best Maternity Hospitals for the second consecutive year, while US News ranked Southcoast among the 10 best hospitals in Massachusetts, and 2nd among those in the Providence Metro area. For three straight years, Southcoast Health has earned Best Hospitals and Best Place to Work in SouthCoast Media Group's Best of the Best Awards, voted on by residents and readers.

With upward of 7,500 employees, Southcoast Health is the largest employer in southeastern Massachusetts, and one of the largest employers in the Commonwealth, according to the Boston Business Journal. More information is available online at www.southcoast.org. Connect to Southcoast Health through social media on Facebook, Twitter, Instagram, and LinkedIn. Southcoast® is a registered trademark of Southcoast Health System.