

Study launched by STSI uses wearable sensors to detect AFib

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Researchers at the Scripps Translational Science Institute (STSI) have launched a home-based clinical trial that uses wearable sensor technology to identify people with asymptomatic atrial fibrillation (AFib).

The primary objective of the mHealth Screening To Prevent Strokes (mSToPS) study is to determine whether screening select individuals in their homes using wearable sensor technology can identify people with asymptomatic AFib more efficiently than routine care, such as regular visits to a [primary care physician](#) to address general health issues.

"This is a uniquely targeted and participant-centric trial that takes full advantage of digital technologies, including large medical data sets and wearable sensors," said Steven Steinhubl, M.D., director of digital medicine at STSI and principal investigator of the mSToPS trial. "Once completed, it has the potential to truly change the practice of screening and markedly improve outcomes."

STSI is a National Institutes of Health sponsored consortium led by Scripps Health in collaboration with The Scripps Research Institute. Through this innovative partnership, Scripps is leading the effort to translate wireless and genetic medical technologies into high-quality, cost-effective treatments and diagnostics for patients.

According to the Centers for Disease Control and Prevention, as many as six million Americans live with AFib, which is an irregular heartbeat

(arrhythmia) that can lead to a five-fold increased risk of stroke and other severe health-related complications. In fact, one in three people with AFib will have a stroke in their lifetime, making it a significant health burden worldwide.

While effective therapies exist to help reduce the risk of stroke in patients with AFib, the condition remains notably underdiagnosed. With as many as 30 percent of all cases of AFib undiagnosed, more effective methods of screening are needed to help reduce AFib associated mortality, morbidity and costs.

In a novel multisectoral collaboration, STSI has teamed with Aetna's Innovation Labs and Healthagen Outcomes units and Janssen Pharmaceuticals, Inc., to conduct the study.

Up to 2,100 participants will be recruited for active monitoring through the Aetna Commercial Fully Insured and Medicare programs, and an additional 4,000 people will be identified as observational controls. Women over the age of 65 and men over 55 will be selected to participate based on information derived from claims data that places them at a potentially increased risk of undiagnosed AFib.

During the four-month monitoring period, participants will undergo continuous single-lead electrocardiogram (ECG) monitoring using the ZIO® XT Patch [wearable sensor](#), developed by iRhythm Technologies, for the first two weeks and last two weeks of the monitoring period.

In order to explore multiple innovative technologies for heart rhythm detection, a subset of participants also will be invited to participate in a substudy to monitor heart rate and rhythm characteristics through the Amiigo wristband monitor. The participants in the substudy will be asked to wear that device daily, as much as possible through the entire four-month monitoring period.

"Digital sensors are a vital part of the future of medicine," STSI Director Eric Topol, M.D., said. "The mSToPS trial has the potential to upgrade and refine our approach in screening for heart arrhythmias, and at the same time demonstrate the value of large, real-world clinical trials using an array of digital medicine technologies."

More information about the mSToPS trial is available at <http://www.ClinicalTrials.gov> (Study Identifier: NCT02506244).

Provided by Scripps Health

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