



Study Published in JAMA Cardiology Finds Zio by iRhythm Proactively Identifies Atrial Fibrillation, Increases Detection Tenfold

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Wearable cardiac monitoring solution enables early detection and treatment of arrhythmia based on risk factors, according to results of the SCREEN-AF study

SAN FRANCISCO, Feb. 24, 2021 (GLOBE NEWSWIRE) -- iRhythm Technologies, Inc. (NASDAQ:IRTC), a leading digital healthcare solutions company focused on the advancement of cardiac care, today announced that the results of the "SCREEN-AF" study led by researchers at Sunnybrook Health Sciences Centre in Toronto, Canada and University Hospital in Leipzig, Germany were published today in *JAMA Cardiology*.

The transatlantic clinical trial found that [Zio by iRhythm](#), an ambulatory cardiac monitoring solution, led to a tenfold increase in the detection of atrial fibrillation (AF) versus patients receiving standard clinical care. One out of every 20 patients in the heart monitoring group was found to have a new diagnosis of atrial fibrillation and, as a result, 75 percent of those patients were subsequently prescribed a blood thinner medication for protection against strokes.

The study results lend support for Zio as a screening tool for early detection of AF. The results have important implications for stroke prevention, especially as the prevalence of AF and AF-associated strokes is increasing with the aging of the population. Zio was found to be well tolerated and effective, and the service's diagnostic reports enabled appropriate patients to receive anticoagulant therapy (anti-clotting medication) which has the potential to avert future strokes.

"Approximately one-third of those who have AF are not aware that they have it, leaving them at a significantly elevated risk of stroke," said Michael Coyle, CEO at iRhythm. "The clinical validation that iRhythm has seen through its recent trials – mSToPS and SCREEN-AF – demonstrates that Zio proactively identifies arrhythmias based on risk factors, helping undiagnosed populations remotely monitor their symptoms and effectively seek treatment before more serious problems can occur."

Unlike handheld ECGs, watches, and blood pressure monitors, wearable continuous ECG devices can serve as both a screening tool and a diagnostic test, likely reducing the need for confirmatory testing. When compared with implanted cardiac monitors, wearable ECG devices are noninvasive, less costly, more accessible, and can be self-applied by patients at home.

"The big challenge is that atrial fibrillation is often a silent risk factor that can be difficult to detect with current methods," says Dr. David Gladstone, the study's principal investigator and stroke neurologist from Sunnybrook Health Sciences Centre and Department of Medicine in the University of Toronto Temerty Faculty of Medicine. "If we are able to better detect atrial fibrillation, then more people could receive treatment for it earlier, and more strokes ought to be prevented," adds Dr. Gladstone, who recently presented the research findings at the World Stroke Congress.

"These results are an important step towards stroke prevention by early detection of atrial fibrillation," said Dr. Rolf Wachter, co-principal investigator, cardiologist at the University Hospital in Leipzig, Germany and scientist at the German Center for Cardiovascular Research.

The study recruited 856 individuals from 48 primary care clinics between 2015 and 2019. It involved participants aged 75 years or older who had high blood pressure but no previous diagnosis of AF. Half of the participants were given Zio monitors to wear at home for up to four weeks, while the other half of participants received standard medical care. All participants were observed for six months.

Clinical collaboration was supported through Sunnybrook Health Sciences Centre, the German Center for Cardiovascular Research, the Heart Center in Göttingen, and the Population Health Research Institute.

Read the study manuscript [here](#).

About Atrial Fibrillation

Atrial fibrillation (AF or AFib) is a quivering or irregular heartbeat, also known as an arrhythmia, which can lead to blood clots, stroke, heart failure, and other heart-related complications. Normally, the heart contracts and relaxes to a regular beat. In AF, the upper chambers of the heart (the atria) beat irregularly instead of beating effectively to move blood into the ventricles.

iRhythm estimates more than 10 million Americans are at high risk for AF. With the aging of the U.S. population, this number is expected to increase. AF is associated with up to a five-fold increase¹ in the risk of stroke, with these strokes tending to be severe and often associated with high mortality. However, approximately one-third² of those who have AF are not aware that they have it.

For many individuals who experience a stroke due to AF, the occurrence of AF was not diagnosed until the time of their stroke or shortly afterward. Asymptomatic or undiagnosed AF is referred to as being "silent" and there are certain risk factors like aging and high blood pressure that increase an individual's likelihood of developing it.

About the SCREEN-AF Study

SCREEN-AF was an investigator-initiated and investigator-led academic clinical trial that evaluated home-based atrial fibrillation screening in older primary care patients with hypertension. A wearable LT-ECG strategy for up to four weeks detected a substantial prevalence (5%) of subclinical AF, was superior to six months of standard clinical care for AF detection, and resulted in more patients prescribed anticoagulant medication for stroke prevention. Most AF cases were paroxysmal, with episodes lasting many hours. Patient adherence to LT-ECG was high; three-quarters of AF cases were detected within the first two weeks of ECG monitoring, and 90% of cases would have been missed using a 24-hour Holter monitor alone.

[ClinicalTrials.gov](#) Identifier: NCT02392754

About iRhythm Technologies, Inc.

iRhythm is a leading digital healthcare company redefining the way cardiac arrhythmias are clinically diagnosed. The company combines wearable biosensor devices worn for up to 14 days and cloud-based data analytics with powerful proprietary algorithms that distill data from millions of heartbeats into clinically actionable information. The company believes improvements in arrhythmia detection and characterization have the potential to change the clinical management of patients.

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¹ Wolf PA, Abbott RD, Kannel WB. Atrial fibrillation as an independent risk factor for stroke: the Framingham Study. *Stroke*. 1991;22(8):983–8.

² Friberg L, Rosenqvist M, Lindgren A, Terént A, Norrving B, Asplund K. High prevalence of atrial fibrillation among patients with ischemic stroke. *Stroke* 2014;45:2599-605.

