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NEWS RELEASE

AMALFI Randomized Clinical Trial Results Demonstrate Increased Atrial Fibrillation Diagnosis with Home-Based Long-Term Continuous ECG Monitoring Using iRhythm Technologies' Zio LTCM Service

2025-08-29

- Oxford University-led AMALFI clinical trial results presented at the European Society of Cardiology (ESC) Congress 2025 and published in the Journal of the American Medical Association (JAMA).
- AMALFI tested whether home-based, self-applied use of iRhythm's Zio long-term continuous monitoring (LTCM) device and service could improve diagnosis of atrial fibrillation (AFib) in 5040 participants in the United Kingdom (UK).
- A remote screening strategy with the Zio LTCM service led to an increase in AFib detection and shorter time to diagnosis versus usual care. Findings confirm efficacy of Zio LTCM service for AFib detection in patients at moderate to high risk of stroke, generalized to a UK population using home-based device application and activation.

SAN FRANCISCO, Aug. 29, 2025 (GLOBE NEWSWIRE) -- **iRhythm Technologies, Inc.** (NASDAQ:IRTC) announced results from the Oxford University-led Active Monitoring for AtriaL FIbrillation (AMALFI) randomized clinical trial, presented at the European Society of Cardiology (ESC) Congress 2025 and simultaneously published in the **Journal of the American Medical Association (JAMA)**, demonstrating that home-based screening with the Zio® long-term continuous monitoring (LTCM) service led to increased atrial fibrillation (AFib) detection and a shorter time to diagnosis.

AMALFI was a prospective, parallel group, randomized controlled trial designed to test whether home-based screening for AFib in people aged ≥65 years at moderate to high-risk stroke risk factors, using an on-label Zio XT LTCM device with monitoring up to 14 days, could improve AFib detection compared to usual care over 2.5 years of follow-up. Participants were randomized, half were assigned to wear the Zio LTCM device for 14 days in addition to

their usual care, while the other half continued with their usual care and did not receive a monitoring device. The study enrolled 5,040 eligible participants identified via an automated search of electronic records in 27 participating primary care practices in the United Kingdom (UK), and was an entirely remote study, with no physical study sites or in-person visits. Compared to prior screening trials, AMALFI enrolled patients with a higher comorbidity burden: 73% were age ≥75, 19% had a prior stroke or transient ischemic attack, 28% had diabetes, and 18% had chronic kidney disease. Still, in this older population who self-applied the device at home, the median wear time of the Zio LTCM device in the intervention arm was 13.9 days and with a high (98.8%) analyzable time.

At 2.5 years of follow-up, the study found that home-based screening with the Zio LTCM service led to a modestly higher increase in new diagnosis of AFib in 172/2520 (6.8%) participants in the intervention arm vs 136/2520 (5.4%) participants in the control arm (ratio of proportions 1.26, 95% CI 1.02-1.57, p=0.03), and a faster time to diagnosis with AFib recorded at a median of 103 days (IQR 43-539) in the intervention arm vs 530 days (IQR 276-688) in the control arm, using an intention to screen analytic approach. Participants in the intervention arm were more likely to be prescribed oral anticoagulation for stroke prevention, with an average of 1.63 months exposure compared to 1.14 months in the control arm over the study period (difference 0.50 months, 95% CI 0.24-0.75, p<0.001).

“Atrial fibrillation can be difficult to detect as it often occurs without symptoms or infrequently. New technology enables home-based, longer-duration monitoring that can identify episodes which might otherwise be missed,” said Louise Bowman, Professor of Medicine and Clinical Trials at Oxford Population Health and co-author of the study. “AMALFI showed that home-based monitoring is feasible and provides evidence that it can be initiated at scale using primary care health records with minimal burden on patients and practices.”

AFib is a common but often undiagnosed heart rhythm disorder that substantially increases the risk of stroke, heart failure, cardiovascular hospitalization, and health care utilization, making early detection and timely treatment vital to reduce stroke risk, ensure heart rate control, and restore normal sinus rhythm. As the National Health Service (NHS) in the UK is placing greater emphasis on disease prevention and early detection and has prioritized a shift toward upstream care by moving resources into community and primary care, the study has notable implications:

- Screening with Zio LTCM results in earlier and more frequent AFib diagnosis. In AMALFI, screening with the Zio LTCM service led to an increase in detection of AFib versus usual care (6.8 vs 5.4%) that was sustained over long-term follow up, and a faster time to diagnosis versus usual care (103 vs. 530 days). The primary endpoint was assessed over 2.5 years, providing ample opportunity for AFib detection in the control group through usual care. Yet even with this lengthy follow-up period, the benefit of a single 14-day monitor at baseline was sustained, supporting the durability of the intervention effect. AMALFI was not powered to detect differences in clinical outcomes, such as stroke.
- Primary care–initiated, home-based diagnostic monitoring is feasible. AMALFI was an entirely remote study

with no physical sites or in-person visits. Participants were identified through an automated search of electronic health records in primary care practices. Participants in the intervention group received Zio LTCM devices by mail, self-applied them at home, wore them for 14 days, and returned them by post for analysis.

The Zio LTCM service has been available in the US since 2008 and was introduced in the UK in 2014. In the UK, the service consists of the Zio XT wearable sensor, a single-use ambulatory ECG patch monitoring device worn for up to 14 days to capture continuous, uninterrupted data. Recorded data is processed using a UKCA-marked deep-learned algorithm that detects 13 arrhythmia types plus sinus rhythm and artifact and is then curated and verified by qualified cardiographic technicians to generate a Zio end-of-wear report that helps clinicians make the right diagnosis the first time.[1-4] Designed to be simple to self-apply and wear during daily activities, the Zio LTCM service is available for home enrollment—allowing patients to receive and apply the device at home without visiting a clinic—and can also be initiated in the primary care setting.

“Patients at our clinic benefit from home-based monitoring with the Zio device, which is easy to apply and use, allowing their entire diagnostic journey to take place without repeated trips to the clinic and fitting easily into daily life,” said James Rosengarten, MBBS MRCP DM, Consultant Cardiologist and Electrophysiologist, East Kent Hospitals University NHS Foundation Trust in the UK. “At the same time, the Zio service provides clinicians with clear, high-quality insights that streamline diagnosis and help ensure timely, effective care.”

“The AMALFI results show that home-based, long-term continuous monitoring with Zio can improve the timely detection and diagnosis of atrial fibrillation,” said Mintu Turakhia, MD, Chief Medical and Scientific Officer and EVP of Advanced Technologies at iRhythm. “These findings add to the growing evidence that population health approaches to identify undiagnosed arrhythmias can be implemented at scale — demonstrated here through primary care in the UK — and can enable prompt therapy such as anticoagulation, rate and rhythm control, and cardiovascular risk factor reduction.”

These published results add to iRhythm’s comprehensive clinical evidence program, encompassing more than 125 original research manuscripts,[5] insights derived from over 2 billion hours of curated heartbeat data[6] and more than 10 million patient reports posted since the company’s inception—underscoring an ongoing commitment to expanding evidence that supports improved patient outcomes.

Funding for the trial was provided by the National Institute for Health and Care Research (NIHR) Oxford Biomedical Research Centre and the British Heart Foundation. iRhythm Technologies (San Francisco, CA) supported the study by providing the Zio LTCM service (Zio® XT monitoring devices, ECG analysis and cardiac technician data review) at no charge.

Editor Notes:

“AMALFI: Active monitoring for atrial fibrillation” will be presented at the European Society of Cardiology (ESC) Congress 2025 during **HOT LINE 1** on Friday 29 August 2025 at 11:15 CEST (10:15 BST).

The rationale, protocol and pilot study are described in: Wijesurendra R, Pessoa-Amorim G, Buck G, et al. Active Monitoring for AtriaL FIbrillation (AMALFI): rationale, protocol, and pilot for a pragmatic, randomized, controlled trial of remote screening for asymptomatic atrial fibrillation. Am Heart J. 2025;doi:10.1016/j.ahj.2025.07.004.

For further information on AMALFI study outcomes, interviews or images, please **contact Anne Whitehouse**, Director of Communications and Public Engagement, Oxford Population Health (the Nuffield Department of Population Health, University of Oxford), tel +44 (0)1865 289474 / +44 (0)7812 165934.

For further information on atrial fibrillation, role of ambulatory cardiac monitoring, or Zio LTCM device and service, interviews or images, please **contact Kassandra Perry**, Director of PR/External Communications, iRhythm Technologies.

About iRhythm Technologies, Inc.
iRhythm is a leading digital health care company that creates trusted solutions that detect, predict, and prevent disease. Combining wearable biosensors and cloud-based data analytics with powerful proprietary algorithms, iRhythm distills data from millions of heartbeats into clinically actionable information. Through a relentless focus on patient care, iRhythm’s vision is to deliver better data, better insights, and better health for all. To learn more about the Zio® LTCM service the UK, please visit **iRhythmTech.com/gb/en**. Outside of the UK, iRhythm offers its Zio® portfolio of cardiac monitoring solutions in Austria, Japan, the Netherlands, Spain, Switzerland, and the United States. For additional information about iRhythm Technologies, please visit its corporate website at **iRhythmTech.com**.

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[1] Data on file. iRhythm Technologies, 2020.

[2] Hannun et al. Cardiologist-level arrhythmia detection and classification in ambulatory electrocardiograms using a deep neural network. Nat Med. 2019;25:65-69. **https://doi.org/10.1038/s41591-018-0268-3**

[3] Deep learned algorithm is only available in the United States, European Union, Switzerland, United Kingdom, and Japan.

[4] FDA 510K clearance, CE mark, UKCA mark, and PMDA-approval.

[5] Data on file. iRhythm Technologies, 2025.

[6] Data on file. iRhythm Technologies, 2024.

Source: iRhythm