

Stroke Prevention: Atrial Fibrillation Screening

The zensor)) vital signs monitoring system delivers a convenient and reliable method of diagnosing Atrial Fibrillation in a high risk population



Impact of Atrial Fibrillation

Atrial Fibrillation (AF) is the most commonly occurring cardiac arrhythmia¹. It is currently estimated that 2% of the general population, and 10% of those over 75 have AF¹.

Early results in an Irish AF screening study could nearly double this estimate.

By 2030 there could be 494,000 new cases of AF in the UK every year according to incidence estimates. The prevalence of AF could rise to 2.3 million people living with the arrhythmia in the UK². It has been described as an epidemic by the AF Association. While there are many costs associated with AF - physical, psychological and financial, the most serious and damaging consequence to the patient, their families and our healthcare services is the increased risk of Stroke. People with AF have a 5 times greater chance of having stroke and up to 30% of all strokes result directly from AF³.

If strokes arising because of AF were prevented, the UK NHS could save nearly £60m per year in direct stroke costs alone.

The Trial's hypothesis has been supported in the first group of 150 patients with significant numbers of those screened being found to have previously undiagnosed AF

Currently, in the United States and Europe AF is diagnosed when:

- (i) The patient presents with palpitations or other symptoms (symptomatic) such as breathlessness or fatigue.
- (ii) The patient has had a stroke and is monitored for atrial fibrillation
- (iii) Opportunistic screening undertaken by GPs

Due to the significance of AF as a preventable risk factor for stroke it is strongly believed by the medical community that there should be a systematic screening programme for this arrhythmia in the at-risk population, particularly as AF fits the Wilson-Jungner criteria set out by the WHO for a screening programme⁴. Dr Robert Kelly, Consultant Cardiologist and Dr Rónán Collins, Consultant Geriatrician and Stroke Physician have designed a screening study to confirm the efficacy of screening patients with pre-existing associated risk factors. Dr Rónán Collins explains:



"Atrial Fibrillation (A-Fib or AF) is a rhythm disorder of your heart which is very common as we age. AF acts like a "wonky" cement mixer so that blood (the cement) in your heart (the mixer) is not stirred enough. This can result in the "lumps in your cement" or clots in your blood within your heart chamber which can fall into the pump of your heart and be 'fired down the pipework' until getting stuck, blocking flow and causing stroke. AF can be detected by checking your pulse (see <http://www.irishheart.ie> to find out how) or by monitoring your heart for a period of days. AF can occasionally be converted to a regular rhythm or the blood thinned ('cement watered down') to prevent clots forming and reduce the risk of stroke".

Dr Rónán Collins

Leading cardiologist, Dr Robert Kelly, who has developed the ground breaking protocol, comments on the challenges associated with AF diagnosis and the need for undertaking the study:



"Currently there is no medical basis for providing anticoagulation treatment in at-risk patients without a diagnosis of Atrial Fibrillation. The Afib Screening for Stroke Study is therefore very important because it seeks to establish the prevalence of AF in high risk patients in the community i.e. patients with Diabetes, High Blood Pressure or Congestive Heart Failure. To do this, a novel non-invasive heart monitor called zensor)) will be used to screen patients for AF. It is an approved, state-of-the-art device; its design is compact and easy to wear for patients. The key advantages of this device are that it will monitor patients' heart rhythms via patch based wearable smart sensors for 7 days. Heart rhythm data is sent to the clinician using Wi-Fi technology. The clinician accesses the data using his computer or tablet to review any events detected by the non-intrusive, wearable device. With current Holter technology the same screening is very unreliable, prone to motion artefact and analysis can take several weeks to assess for the presence of AF".

Dr Robert Kelly

Encouraging Study Progress

The first stage of the trial is screening up to 320 patients, controlled from the clinics run at the Beacon Hospital in Sandyford and the AMNCH Hospital in Tallaght, Dublin. At this stage, nearly half of the patients have been screened. If a patient is diagnosed with AF they are referred back to their GP to review treatment options.

Patient recruitment has been extended to include patients from Wexford and Waterford. It is expected that the study will expand to enrol 1,000 patients. On completion of the study, a full economic and feasibility analysis will also finalise to ensure that benefits are confirmed to include both clinical and economic gains.

The Monitoring Device: zensor))

zensor)), the vital signs monitor being used in the trial, is designed and manufactured by Belfast-based company Intelesens Ltd. Their cutting-edge technology utilizes multiple features ensuring the highest sensitivity algorithms for the detection of arrhythmia. Never before have motion and respiration been included in a body-worn ECG device. The patient can be screened without interrupting their normal daily routines. Patient feedback shows that the electrode patch-based device is much lighter and more comfortable than existing devices such as the Holter Monitor.

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Other partners include:

National Cardiovascular and Stroke Research Network Ireland (NCSRNI)
Clinical Research Ireland (CRI)
Dublin Centre for Clinical Research (DCCR)
BioBusiness Ltd.



References:

- [1] Atrial Fibrillation Association (AFA) and AntiCoagulation Europe (ACE), The AF Report. Atrial Fibrillation: Preventing a Stroke Crisis. Available at: <http://www.preventaf-strokecrisis.org/> Accessed 08th Aug 2014
- [2] Colilla, S et al. Estimates of current and future incidence and prevalence of atrial fibrillation in the US adult population. American Journal of Medicine 2013;112(8):1142-7
- [3] Marini, C et al. Contribution of atrial fibrillation to incidence and outcome of ischemic stroke: results from a population-based study. Stroke 2005;36: 1115-19
- [4] Wilson, JMG and Jungner, G. Principles and Practice of Screening for Disease. J R Coll Gen Pract Oct 1968; 16(4): 318



zensor)) Features:

- 3-Lead ECG
- Respiration waveform and rate
- 3-Axis accelerometer for motion
- Motion artefact reducing electrodes
- Automatic arrhythmia detection
- Patient activated recording
- Wi-Fi Event Transmission

For more info, please visit: www.zensor.co.uk.



This study is recruiting

If you, or someone you know, are over the age of 60 and have a history of high blood pressure, diabetes or congestive heart failure, you may be suitable for inclusion in this study. If you are interested in finding out more information, please contact the study research team on

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