Title: An RCT to determine if screening for paroxysmal atrial fibrillation reduces stroke and mortality: SAFER programme “Screening for Atrial Fibrillation with ECG to Reduce stroke

Problem: Atrial Fibrillation (AF) is a major risk factor for ischaemic stroke unless treated with an anticoagulant. Detecting AF can be difficult because it is often paroxysmal and asymptomatic. Many clinicians support AF screening. The UK National Screening Committee and the US Preventive Services Task Force have highlighted a lack of evidence that screening for AF is beneficial. The 8-year NIHR-funded SAFER Programme aims to determine if screening for AF in people aged ≥65 years does prevent stroke, does not cause significant harm, and is cost-effective.

Approach: Patients will attend their GP practice for instruction in the use of a handheld single-lead ECG device (Zenicor). They will continue screening at home over a 2-4 week period. The ECGs will be read by a validated computer algorithm with diagnoses confirmed by a cardiologist. Treatment for AF will follow national guidelines.

1. Feasibility study (commenced February 2019)

In 12 practices all allocated to screening to determine whether it is feasible to implement screening within primary care.

2. Internal pilot trial

Cluster randomising practices (10 screening, 20 control) to inform refinement of the screening programme, determine the AF detection rate and inform the power calculation for the main trial.

3. Main trial

Cluster randomising practices (100 screening, 200 control; 120,000 patients). Average 5-year follow-up of electronic medical records will determine if screening leads to fewer strokes, heart attacks and deaths, and whether it increases the risk of serious bleeding.

4. Qualitative

Interviews and observations with patients and staff to clarify how to best carry out screening. Exploration of psychological harms of screening.

5. Health economics

A within trial analysis and decision modelling analysis to determine whether screening is cost effective.

Findings: Due to report in 2027, this is the world’s largest planned AF screening trial to date.

Implications: If cost-effective, an AF screening programme with careful management of diagnosis and treatment may prevent over 10% of ischaemic strokes. The SAFER programme will inform the decision regarding possible implementation of a national AF screening programme.

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