ISRCTN55722437 https://doi.org/10.1186/ISRCTN55722437

Automated risk assessment for stroke in atrial fibrillation

Submission date 21/02/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/02/2013	**Overall study status** Completed	
Last Edited 26/01/2017	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Atrial fibrillation is a heart condition that causes an irregular and often abnormally fast heart rate. Patients with atrial fibrillation (AF) can be 5 times more likely to suffer a stroke. Oral anticoagulants (blood thinning agents) reduce this risk by up to 70 percent. Despite this benefit to the patients, anticoagulants remain under-prescribed in UK primary care. Recent estimates place prescribing at 53 percent of those potentially eligible, whilst over 30 percent of patients remain both without a prescription, and without a recorded reason. We aim to see whether an automated software system, operating within general practices' electronic medical records, will improve management of atrial fibrillation by identifying patients eligible for anticoagulation and increasing prescriptions.

Who can participate?
The study aims to recruit 46 general practices operating the EMIS-Web clinical system, which will be included in the main phase of the trial. Before this, we will carry out a pilot study including 3 practices. Within the study, we will interview 30 patients in the participating practices and 10 general practitioners.

What does the study involve?
We will randomly allocate practices to use an electronic software tool or to continue with usual care. The tool will a) produce (and continually refresh) a list of patients with atrial fibrillation eligible for therapy - practices will invite these patients to discuss treatment at the start of the trial; b) generate electronic on-screen reminders in the medical records of those eligible, appearing throughout the trial. We will run the tool for 6 months, in 23 of the practices. The other 23 practices will manage their atrial fibrillation register as usual. We will find out how many eligible patients with atrial fibrillation have been prescribed anticoagulation therapy after six months. We will also look at incidence of stroke, transient ischaemic attack, other major thromboembolism, major haemorrhage (bleed) and reports of inappropriate anticoagulant prescribing. We will also look at patient and practitioner views of the intervention; its impact on care and the general practice - notably its time implications.

What are the possible benefits and risks of participating?
Participating practices will, if allocated to the treatment arm, have use of a software tool

designed to assist them in improving care in an important clinical area. If the intervention is found to be effective and safe, control practices will also be offered the opportunity to use it after the trial. Depending on the results of the trial, the intervention could be made available to all UK primary care centres. We foresee two main potential risks for practices; harm from the electronic reminder system to the consultation process, such as negative impacts on the length and flow of consultations and reducing patient choice. Secondly, there is a risk of prescribing anticoagulants in patients who are unsuitable for anticoagulation, despite being apparently eligible. We will monitor these carefully during the trial.

Where is the study run from?
The Department of Primary Health Care Sciences at the University of Oxford with local support from the Universities of Birmingham and Nottingham (UK)

When is the study starting and how long is it expected to run for?
We propose to begin the 3 month pilot study on 1st April 2013, recruiting practices in the month before to this. We shall recruit practices for the main-phase from March to May 2013, aiming to begin the 6-month intervention period on 1st July 2013. The trial is expected to end by 30th June 2014.

Who is funding the study?
NIHR School for Primary Care Research (UK)

Who is the main contact?
Dr. Andrew R H Dalton
andrew.dalton@phc.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Andrew Dalton

Contact details
Department of Primary Care Health Sciences
Radcliffe Observatory Quarter
Woodstock Road
Oxford
United Kingdom
OX2 6GG
-
andrew.dalton@phc.ox.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13972

Study information

Scientific Title
Automated Risk Assessment for Stroke in Atrial Fibrillation: a cluster randomised controlled trial of an electronic reminder intervention to promote anticoagulation and reduce stroke risk (AURAS-AF)

Acronym
AURAS-AF

Study objectives
An automated software system, operating within electronic medical records in primary care, that identifies patients with atrial fibrillation who are eligible for oral anticoagulant therapy, will increase the uptake of therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Berkshire, 11/02/2013, ref: 13/SC/0026

Study design
Cluster-randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Stroke

Interventions
Intervention will have a piece of software activated in their primary carer databases. The software will generate a list of all patients registered in the practice diagnosed with atrial

fibrillation, who are deemed eligible for anticoagulation (based on criteria in NICE TA249) but not currently prescribed it. Practices will invite these patients (excluding those clearly unsuitable) for a consultation to discuss anticoagulation. They will include an information sheet about anticoagulation, provided by the study team, in the invite. Practices will send reminders to non-attenders one month into the study.
The tool will also produce pop-up reminders whenever patients (on the list above) medical records are opened. These remind the member of the practice team to discuss anticoagulation. The reminders will appear throughout the trial until they are resolved. Pop-ups must be addressed in order to continue using the medical record, with one of 5 options taken.

Control practices will manage patients on their atrial fibrillation register in the normal manner, in line with the quality and outcomes framework and clinical guidelines.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Proportion of patients with diagnosed AF and eligible for anticoagulation under recent guidelines (NICE TA249) who are prescribed this therapy six months after the start of the intervention

Secondary outcome measures
Main phase:
1. Proportion of patients with CHADS2 score ≥2 who are prescribed anticoagulants
2. Record of inappropriate care or prescribing decisions related to anticoagulation in patients with AF
3. Incidence of stroke, transient ischaemic attack (TIA), other major thromboembolism or major haemorrhage during the trial
4. Outcomes of the discussion of/ decisions about the prescription of anticoagulants - including number of patients eligible/invited for a discussion about anticoagulation/reasons for not inviting patients/number attending discussion/outcomes of discussion/reasons for not to using OAC

Pilot study:
1. Limitations to usability and appropriateness of intervention and trial material [to improve the intervention, not directly answer objectives
2. Ease of adoption of electronic system by primary care team

Process evaluation:
1. Responses to screen reminders
2. Patient views on opportunistic (using the electronic reminders) and systematic (from the invitation of the eligible list) approaches to anticoagulant prescribing, and views on the appropriateness and usefulness of electronic reminders
3. Practitioner views on the use of electronic reminders and audit lists of eligible patients to promote anticoagulant prescribing, and of their impact on the consultation process

Overall study start date
01/04/2013

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Practices using clinical software compatible with the intervention (i.e. the EMIS-Web system)
2. Within the study region, namely covering the South East of England, Central England and East Midland & South Yorkshire Primary Care Research Networks (PCRNs)
3. Within participant practices, outcome data will be recorded in patients with diagnosed atrial fibrillation, who justify anticoagulation according to the criteria in NICE guidance TA249

For the pilot study the above criteria (as well as the exclusion criteria below) apply, simply confined to the Thames Valley research partnership area.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
UK Sample Size: 49 general practices (46 in the main phase, with a further 3 pilot practices)

Key exclusion criteria
The practice may not enter the study if ANY of the following apply:
1. Practices using other clinical software systems than EMIS-Web
2. Practices have recently (within the last 2 years) carried out a major audit of OAC prescribing in eligible patients, including the systematic invitation of patients, using bespoke software tool such as GRASP-AF
3. Practices previously involved in a trial concerning anticoagulation in AF
4. For the main phase of the trial, practices participating in the pilot will be excluded

Date of first enrolment
01/04/2013

Date of final enrolment
31/05/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Oxford
United Kingdom
OX2 6GG

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Department of Primary Health Care
Institute of Health Sciences
Old Road
Headington
Oxford
England
United Kingdom
OX3 7LF

Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR (UK) - School for Primary Care Research

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/11/2013		Yes	No
Results article	results	01/03/2017		Yes	No
HRA research summary			28/06/2023	No	No