ISRCTN19633732 https://doi.org/10.1186/ISRCTN19633732

Randomised controlled trial and cost effectiveness study of targeted screening versus systematic population screening for atrial fibrillation in the over 65s: the SAFE study

Submission date
25/04/2003

Recruitment status
No longer recruiting

Registration date
25/04/2003

Overall study status
Completed

Last Edited
13/01/2015

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof FD Richard Hobbs

Contact details
Department of Primary Care & General Practice
University of Birmingham
The Medical School
Birmingham
United Kingdom
B15 2TT
+44 (0)121 415 8019
f.d.r.hobbs@bham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 96/22/11

Study information

Scientific Title
Randomised controlled trial and cost effectiveness study of targeted screening versus systematic population screening for atrial fibrillation in the over 65s: the SAFE study

Acronym
SAFE

Study objectives
1. To establish the incremental cost effectiveness of different screening options (targeted or population screening) compared with routine clinical practice for detection of AF in over 65s.
2. To determine the value of clinical factors and echocardiography in the process of risk stratification for thromboembolic disease in patients with AF.
3. To determine optimal method of AF diagnosis and ECG interpretation.
4. To assess implications for service provision should screening for AF become a national programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular diseases: Heart disease

Interventions
Screening vs control.
24,000 patients aged over 65 will be identified from approximately 24 purposefully selected

general practices from the West Midlands. Patient randomisation will result in 5,000 patients invited for screening with 5,000 control patients from the same practice (Principal-control patients). Control practices will provide a further 4,000 control patients (Practice-controls). Prospective identification of pre-existing risk factors for AF within the screened population (estimated at 2,000 patients) will enable comparison between high risk targeted screening and total population screening. Study outcomes will identify the clinical and cost effectiveness of overall screening strategy (2 options compared), actual screening method (4 methods compared), and screening test interpretation (4 options evaluated).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Not provided at time of registration.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/06/2000

Completion date
31/05/2003

Eligibility

Key inclusion criteria
Patients over 65 years

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
15,000

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/06/2000

Date of final enrolment
31/05/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Primary Care & General Practice
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
Quarry Hill
Leeds
United Kingdom
LS2 7UE
+44 (0)1132 545 843
Sheila.Greener@doh.gsi.gov.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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	29/07/2004		Yes	No
Results article	results	25/08/2007		Yes	No
Results article	results	01/06/2014		Yes	No