

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/04/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/01/2015	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

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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