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Can screening programmes for abdominal aortic aneurysm safely be made more efficient by targeting them at people at the highest risk of disease?

Submission date
23/03/2022

Recruitment status
Recruiting

Registration date
20/04/2022

Overall study status
Ongoing

Last Edited
08/10/2025

Condition category
Circulatory System

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
An abdominal aortic aneurysm (AAA) is a swelling of the main blood vessel in the body, the aorta. If an AAA gets too large, it can burst (rupture) and cause internal bleeding. This is usually fatal. If they are found before they burst, AAAs can be repaired by having an operation. To reduce the number of people dying from ruptured AAA, the NHS offers AAA screening to men at the age of 65 (women rarely get AAA). About 280,000 men are invited for screening each year, with one in five men attending for screening. One in every 100 men screened is found to have an AAA. This screening programme costs the NHS about £7.75 million per year. Much of this cost is spent on screening the 99% of men who do not have AAAs. Some men who don't have an AAA also suffer unnecessary worry from the screening invitation and testing process. Smoking is the main risk factor for AAA. As the number of people who smoke has decreased over time, AAAs are becoming less common. In 2010, 1.50% of men screened by the NHS had an AAA, and this fell to 0.97% in 2019. As AAAs become less frequent, AAA screening costs more per person found to have an AAA. Eventually, the NHS will not be able to justify spending money on AAA screening. An alternative, more cost-effective approach is to only invite men for AAA screening if they are at high risk of having an AAA. This is done in the United States, where only men who are current or ex-smokers are invited for AAA screening. This reduces the number of men who are screened. It is not known if this approach misses many men with AAAs in the group who are not offered screening.

Who can participate?
Men invited for AAA screening by the NHS AAA Screening Programme (2013 to date)

What does the study involve?
In this research, we will analyse results from the NHS AAA Screening Programme from 2013-2021. General practice records will be obtained for around one-fifth of the men invited for screening using a process that ensures all men remain anonymous to the research team. By combining the results of AAA screening with general practice records, we will work out what

would have happened if only men with known risk factors for AAA had been invited for AAA screening.
This work will be extended to see if there are other details in general practice records that can be used to identify men at high or low risk of AAA. This information will be used to see if AAA screening can be targeted at groups of men who are at a high risk of having an AAA and, if so, whether such a targeted screening programme will still identify the majority of men with AAAs. The ethics and acceptability of targeted screening will be explored with members of the public.

What are the possible benefits and risks of participating?
None

Where is the study run from?
University of Leicester (UK)

When is the study starting and how long is it expected to run for?
January 2017 to October 2026

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Prof. Matthew Bown, mjb42@le.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
233765

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NIHR130075, IRAS 233765

Study information

Scientific Title
In-silico trials of targeted screening for abdominal aortic aneurysm using linked healthcare data: can the efficiency of the NHS Abdominal Aortic Aneurysm Screening Programme be improved whilst maintaining publicly acceptable levels of disease detection in an ethically acceptable manner

Study objectives
Targeted screening for abdominal aortic aneurysm (AAA) is more efficient than whole population screening.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 30/05/2018, West Midlands - South Birmingham Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 207 104 8143; southbirmingham.rec@hra.nhs.uk), ref: 18/WM/0140

2. approved 06/05/2021, West Midlands South Birmingham REC (The Old Chapel Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 (0)207104 8256; southbirmingham.rec@hra.nhs.uk), ref: 18/WM/0140

Study design
In-silico trial using linked data from AAA screening and primary care

Primary study design
Other

Study type(s)
Screening

Health condition(s) or problem(s) studied
Abdominal aortic aneurysm

Interventions
This is an in-silico trial that will make use of routine healthcare data gathered as part of the NHS AAA Screening Programme linked to primary care records for these men. Between 2013 and 2022 approximately 2 million men were invited for AAA screening in England. With approval from the Health Research Authority Confidentiality Advisory Group the screening records for these men have been linked to primary care data from the Clinical Practice Research Datalink.

Men who have opted out of NHS data sharing for research will not be included in this research. Primary care data is available for approximately 15% of England and therefore the final dataset will contain data around 300,000 individual records.

By linking primary care data with screening outcomes it will be possible to undertake in-silico trials to determine the effectiveness of targeting screening using primary care data to define groups to be invited for screening.

The primary outcome will be the proportional detection of abdominal aortic aneurysm at screening (diagnostic accuracy). Secondary outcomes will be clinical and economic effectiveness of AAA screening. Effectiveness will be estimated using an established discrete event simulation model of AAA screening.

The control group will be whole population screening (the current approach)

The intervention will be targeted screening using primary care data.

The study dataset will be split at random into two parts. Risk factors to use in targeted screening strategies will be identified from one part of the study dataset before testing these in the second part of the study data.

Intervention Type
Other

Primary outcome(s)
Diagnostic accuracy of AAA screening – sensitivity of targeted screening for AAA detection in comparison to whole population screening. AAA detection will be determined from AAA screening records at a single time point

Key secondary outcome(s))
1. Effectiveness of targeted screening – using the baseline of whole population screening the clinical and economic effectiveness of targeted screening will be estimated using a validated discrete event simulation model. Model parameters will be determined from the analysis of AAA screening outcome data at a single time point
2. Diagnostic accuracy will be determined from data provided by the NHS AAA Screening Programme. This consists of attendance for screening and binary screening outcome (attendance yes/no, aneurysm yes/no). The gold standard for diagnostic accuracy will be the observed results from whole population screening. The results of targeted screening will be compared to this with data for AAA screening outcomes for each individual compared across the two strategies at a single time point

Completion date
01/10/2026

Eligibility

Key inclusion criteria
Men invited for AAA screening by the NHS AAA Screening Programme (2013 to date)

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
Men who have opted out of NHS data sharing or NHS AAA Screening Programme research.

Date of first enrolment
01/04/2013

Date of final enrolment
01/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Leicester
University Road
Leicester
United Kingdom
LE1 7RH

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type

Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to restrictions placed upon data sharing within the data sharing agreements and research governance arrangements in place for this research.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		16/07/2025	07/08/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes