# 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	<b>Recruitment status</b> Recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
<b>Registration date</b> 20/04/2022	<b>Overall study status</b> Ongoing	<ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>
Last Edited 17/07/2025	<b>Condition category</b> Circulatory System	<ul> <li>Individual participant data</li> <li>[X] Record updated in last year</li> </ul>

#### 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

#### Study website

https://www2.le.ac.uk/departments/cardiovascular-sciences/people/bown/copy\_of\_datalinkage-in-the-nhs-aaa-screening-programme

### **Contact information**

**Type(s)** Principal Investigator

**Contact name** Prof Matthew Bown

**ORCID ID** https://orcid.org/0000-0002-6180-3611

**Contact details** University of Leicester BHF Cardiovascular Research Centre Glenfield General Hospital Leicester United Kingdom LE3 9QP +44 116 252 3190 mjb42@le.ac.uk

### Additional identifiers

EudraCT/CTIS number

#### Nil known

IRAS number 233765

**ClinicalTrials.gov number** Nil known

Secondary identifying numbers 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

Secondary study design

**Study setting(s)** Medical and other records

**Study type(s)** Screening

Participant information sheet

Not applicable (retrospective study)

#### 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 measure

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

#### Secondary outcome measures

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 Overall study start date 01/01/2017

**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

**Age group** Adult

**Sex** Male

**Target number of participants** 750000

**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 01/10/2026

# Locations

**Countries of recruitment** England

United Kingdom

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

### Sponsor information

**Organisation** University of Leicester

#### **Sponsor details**

University Road Leicester England United Kingdom LE2 7LX +44 1163736508 rgosponsor@le.ac.uk

**Sponsor type** University/education

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

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**

#### Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

#### Intention to publish date

01/11/2025

#### 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?
HRA research summary			28/06/2023	No	No