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Peripheral arterial disease, high blood pressure and aneurysm screening trial

Submission date
24/02/2022

Recruitment status
No longer recruiting

Registration date
01/06/2022

Overall study status
Ongoing

Last Edited
22/06/2023

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 (aorta) in the abdomen. If the swelling gets too large the aorta can burst and this is usually fatal. In order to prevent bursting, AAAs can be repaired with surgery. This is usually carried out when the size of the AAA is more than 5.5 cm in diameter because below this size, the risk of it bursting is lower than the risks associated with surgery. AAAs are usually asymptomatic before bursting but can be easily and safely diagnosed by ultrasound scanning.

People with peripheral arterial disease (PAD) (furred up blood vessels in the legs) and high blood pressure (BP) are at high risk of heart attacks, strokes and other cardiovascular (CV) problems. 30 to 40% of people over the age of 65 years have PAD and/or high BP. At least a third of these people do not know why they have these problems.

Men are invited to an ultrasound scan when they are aged 65 years to check them for an abdominal aortic aneurysm (AAA). Attendance for AAA screening is good, with eight out of ten men attending. The AAA programme represents a good opportunity to identify and treat men with PAD and/or high BP with minimal extra effort. It is known from speaking to men who have been for AAA screening that they think it is a good idea to check for other conditions at the same time. Women are not invited for AAA screening because they rarely get AAAs. This means a different approach will be required to screen women.

The overall aim of the programme is to find out if screening for PAD and high BP at the same time as screening for AAA improves CV health. The main aim of this study is to assess the feasibility of adding PAD+BP screening to AAA screening by assessing attendance for screening. PHAST-F will also provide detailed data to 1) undertake a process evaluation; 2) help plan the delivery of the main trial; and 3) inform the clinical and economic evaluation of the main trial. Screening device(s) identified from an earlier study (as part of this programme) will be road-tested in 3-5 screening units. Men will be interviewed to find out what they think of the new screening and how their screening results might change their behaviour. Women will be included to find out if they would also benefit from PAD and BP screening. The information from the women will be used to apply for research funds to test screening for women as part of a larger, national screening programme for women.

Who can participate?

1. Men aged 65 years invited for AAA and AAA + PAD + BP screening

2. Women aged 60 to 69 years invited for PAD + BP screening
3. Screeners within the UK NHS AAA Screening Programmes and the Pilot PAD + BP Screening Programme

What does the study involve?
Participants complete a questionnaire before screening, a brief questionnaire after screening, a minimal set of questions at the 5-week phone call, and repeat questionnaires at 3, 6 and 12 months and annually up until 5 years. Data is collected from routine electronic health records and hospital/GP records. Participants are asked to wear a GENEActiv activity watch-like device at Leicester only.
Participants attend interviews where the questions will seek to find out: a) their experience and how acceptable they found the different parts of the screening process; b) the psychosocial impact of screening (i.e. the relationship between social factors and thoughts and behaviours); c) their thoughts and actions following a positive screening result for PAD and/or high blood pressure (where relevant) and the likelihood that they think they will engage with cardiovascular risk management strategies. Screeners will give their thoughts on the screening programme.

What are the possible benefits and risks of participating?
Giving up some time to complete the questionnaires and interviews (where relevant). Some people may find discussing thoughts and feelings as part of the interview distressing. The researchers cannot guarantee any direct benefit from participating, but those participating will be helping to make a significant contribution to the research of new NHS screening programmes.

Where is the study run from?
Leicester Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
January 2021 to September 2028

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

Who is the main contact?
Dr Sian Baldock
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
299928

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 299928, CPMS 51100, UoL 0838

Study information

Scientific Title
Peripheral arterial disease, High blood pressure and Aneurysm Screening Trial: a Feasibility study to determine acceptability, uptake and effect of combined peripheral arterial disease, high blood pressure and abdominal aortic aneurysm screening (PHAST-F)

Acronym
PHAST-F

Study objectives
The primary hypothesis to be tested is that screening men for peripheral arterial disease (PAD), high blood pressure (BP) and abdominal aortic aneurysm (AAA) contemporaneously improves health, is acceptable and is cost-effective. WP2 will specifically look at the acceptability, uptake and effect of combined screening.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/12/2021, North of Scotland (2) Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224 558458; gram.nosres@nhs.scot), REC ref: 202121/NS/0147

Study design
Observational cross-sectional multicentre feasibility study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Observation of the impact of PAD and BP screening on CV risk uptake in men and women being screened

Interventions
Observation of a pilot PAD and BP screening programme vs AAA screening in men regarding the impact on attendance. Post-screening (i.e. a non-research activity), men and women in follow up (research activity) will complete questionnaires assessing quality of life, change in medical history, anxiety, activity, healthcare resource, and psychosocial impact.

At attendance for either AAA screening or AAA plus PAD and high BP screening, subjects will be invited to participate in the following studies (as applicable).

Healthcare professionals in primary care will also be interviewed as well as the screeners and screening staff managers.

Please note: PAD+BP screening is part of a Pilot Screening Programme not the research study, due to how screening programmes are run and the primary outcome being attendance for screening.

The follow-up study:
1. At enrolment to the follow-up study, participants will complete a baseline questionnaire
2. After screening, participants will complete a post-screening questionnaire
3. If screened for PAD and high BP and they screened positive for either, participants will be phoned at 5 weeks and asked a further set of questions on their engagement with cardiovascular risk management strategies and whether they have booked an appointment with their GP
4. Participants will be sent a follow-up questionnaire to complete at 3 months, 6 months, 12 months and annually until 5 years. This is the end of the follow-up.
5. Follow-up using electronic health records over 5 years. The end of follow-up is after 5 years.

The qualitative interview study (optional extra on AAA+PAD+BP screening days):
1. After screening, those enrolled in the optional extra qualitative interview study will be interviewed shortly after screening
2. For those that screened positive for PAD and/or high BP, this interview will be repeated at 6 months
3. After screening, the screeners and managers will be interviewed. This interview will be repeated at 3 months. Primary care staff will also be interviewed.

The GENEActiv sub-study (optional extra on AAA+PAD+BP screening days, UHL site only):
1. After screening, those enrolled in the optional extra GENEActiv sub-study and screened positive for PAD and/or high BP will be issued with a GENEActiv activity device monitor (if available) to wear for 7 days and complete an activity diary.
2. The device will be re-issued at 6 months for a repeat reading over a 7-day period.

Intervention Type
Other

Primary outcome measure
1. Attendance measured as part of the Pilot Screening Programme using the UK AAA Screening Programme methods at baseline for all individuals invited, not just participants in the follow-up,

interview, and GENEActiv studies
2. Quality of life measured using EQ-5D-5L at baseline, 3 months, 6 months, 12 months, 2 years, 3 years, 4 years, and 5 years as part of the follow-up study

Secondary outcome measures

1. Prevalence of PAD and high BP measured using a questionnaire at baseline as part of the Pilot Screening Programme and baseline, 3 months, 6 months, 12 months, 2 years, 3 years, 4 years, and 5 years as part of the follow-up study
2. Prevalence of undiagnosed PAD and high BP measured using a questionnaire at baseline, 3 months, 6 months, 12 months, 2 years, 3 years, 4 years, and 5 years as part of the follow-up study
3. Prevalence of untreated PAD and high BP measured using a questionnaire at baseline, 3 months, 6 months, 12 months, 2 years, 3 years, 4 years, and 5 years as part of the follow-up study.
4. Acceptability of screening test measured by a question on a scale of 1 to 10 after screening as part of follow-up study. Acceptability of the screening is also assessed by interview immediately after screening for those that screen positive for PAD and/or high BP. Acceptability is also assessed by interview after 3 months for the managers and again for those that screen positive for PAD and/or high BP at 6 months.
5. Training requirements for AAA+PAD+BP screening determined from the qualitative interviews with screening staff and managers after screening, 3 months, and throughout screening activities and following clinical training under the pilot screening programme
6. Additional time required for PAD+BP screening vs AAA screening in men measured by collecting the start and end times of appointments at the screening appointment as part of the service evaluation of the clinical pilot screening programme
7. Uptake of CV risk management in men and women that screen positive for PAD and/or high BP, measured by questionnaire (including IPAQ) at 3 months, 6 months, 12 months, 2 years, 3 years, 4 years, and 5 years as part of the follow-up study and from activity data collected by wearing the GENEActiv activity device monitor at baseline and 6 months. Uptake of CV risk management will also be assessed by interviews with those that screen positive for PAD and/or high BP after 6 months following a positive screen result.
8. Major adverse CV events (MACE [death/admission from/for angina/myocardial infarction /ischaemic heart disease/stroke]) assessed by questionnaire at 3 months, 6 months, 12 months, 2 years, 3 years, 4 years, and 5 years as part of the follow-up study and as part of routine data collection via NHS Digital or contacting the participant's GP at 1 year, 2 years, 3 years, 4 years, and 5 years.
9. Major adverse limb events (MALE [death/admission from/for lower limb revascularization /major limb amputation]) assessed by questionnaire at 3 months, 6 months, 12 months, 2 years, 3 years, 4 years, and 5 years as part of the follow-up study and as part of routine data collection via NHS Digital or contacting the participant's GP at 1 year, 2 years, 3 years, 4 years, and 5 years
10. Psychosocial impact of screening assessed by interview immediately after screening and again at 6 months for those that screen positive for PAD and/or high BP. It will also be assessed by questionnaire (GAD-7) at 3 months, 6 months, 12 months, 2 years, 3 years, 4 years, and 5 years as part of the follow-up study.
11. Health care resource use and cost effectiveness assessed by questionnaire at 3 months, 6 months, 12 months, 2 years, 3 years, 4 years, and 5 years as part of the follow-up study and as part of routine data collection via NHS Digital or contacting the participant's GP at 1 year, 2 years, 3 years, 4 years, and 5 years as part of the follow-up study.

Overall study start date

01/01/2021

Completion date

01/09/2028

Eligibility

Key inclusion criteria
Men's study:
1. Willing and able to give informed consent
2. Male
3. Aged 65 years or in the year of their 65th birthday
4. In receipt of an invitation to primary routine AAA screening and have attended for screening
5. An ability to understand verbal and written English

Women's study:
1. Willing and able to give informed consent
2. Female
3. Aged 60 to 69 years
4. Registered at the Willows Health group of GP practices under University Hospitals of Leicester (UHL)
5. An ability to understand verbal and written English

Participant type(s)
Patient

Age group
Adult

Lower age limit
65 Years

Sex
Both

Target number of participants
Invited: 2934 men and 2934 women; Attendance: 2200 men and 2200 women; Follow-up: 1100 men and 1100 women; qualitative interviews 40 men and 40 women; qualitative interviews: 4 screening staff managers; qualitative interviews: 30 screening staff

Key exclusion criteria
Men's study:
1. Men being re-invited for a second appointment having not attended for their primary screening appointment (unless involvement with the study specifically requested upon re-invitation)

Date of first enrolment
17/02/2022

Date of final enrolment
30/09/2024

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
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CB2 0QQ

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
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Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
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Study participating centre
NHS Greater Glasgow and Clyde
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Sponsor type
University/education

Website
https://www2.le.ac.uk/colleges/medbiopsych/research/researchgovernance

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

1. Planned publication in a high-impact peer-reviewed journal
2. Publication on website

Intention to publish date

31/01/2029

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Men single screening version 1.4	09/12/2021	14/03/2022	No	Yes
Participant information sheet	Men triple screening version 1.4	09/12/2021	14/03/2022	No	Yes
Participant information sheet	Women version 1.4	09/12/2021	14/03/2022	No	Yes
HRA research summary			28/06/2023	No	No