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ATTACK: Aspirin to prevent a first heart attack or stroke in people with chronic kidney disease

Submission date
05/10/2018

Recruitment status
No longer recruiting

Registration date
08/10/2018

Overall study status
Completed

Last Edited
01/05/2025

Condition category
Urological and Genital Diseases

[X] 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
We are doing this research to find out whether people with chronic kidney disease (CKD) should take a daily low-dose aspirin tablet to reduce the risk of a first heart attack or stroke. CKD is a term used by doctors when the kidneys are not working as well as they should. It is very common and affects as many as one in eight adults in the UK. CKD is particularly common in older people and in those with diabetes and high blood pressure. CKD is important because it is linked to a much higher chance of heart attacks and strokes. The risk of heart attack or stroke in people with mild CKD is double the risk in people with normal kidney function. The risk increases to five times as high as CKD worsens. We therefore need to find ways to reduce these risks. Heart attacks and strokes are usually caused by small blood clots. Aspirin thins the blood. This reduces the chance that clots will form in the blood but also leads to an increased risk of bleeding. Studies in people with previous heart attacks or strokes show that aspirin reduces the risk of further attacks, and that these benefits are much greater than the risks of bleeding. As a result, aspirin is recommended for people (both with CKD and without CKD) who have already had a heart attack or stroke. Aspirin is less beneficial in preventing a first attack or stroke in the general population and is generally not recommended for this purpose. As heart attacks and strokes are far more common in people with CKD than in the general population, we would expect aspirin to be of greater benefit, but the risks may also be higher as bleeding is more common in people with reduced kidney function. Before we can recommend aspirin treatment to help a first heart attack or stroke in people with CKD, we need to be sure that the benefits of treatment outweigh the possible risks.

Who can participate?
Adults with chronic kidney disease

What does the study involve?
People who are eligible and consent to taking part in the trial will allocated at random to take low-dose aspirin (75mg) once daily (in addition to regular prescribed medication) or continue with regular medication alone. There will be equal numbers in these two groups. Once the study starts, we will find out whether trial participants have had a heart attack or stroke or

experienced any episodes of bleeding by analysing their GP and hospital electronic records. A basic health questionnaire will be sent for completion once a year. Patients will not be asked to attend any additional appointments.

What are the possible benefits and risks of participating?
Until we complete the research, we will not know whether taking aspirin benefits people with CKD. Taking part in the study may not benefit participants personally, but the information we get will improve the treatment of people with CKD in the future. As well as helping patients, we believe that this trial is also important as it may lead to major cost savings for the NHS. This is because aspirin is an inexpensive drug and the costs of heart attack and stroke in people with CKD are very high (up to £1 billion per year). Low dose aspirin is generally safe but like all drugs, aspirin can have side effects. The side effects of aspirin are well known. The most common side effects are indigestion and irritation of the stomach. The most important side effect is bleeding, particularly from the stomach and intestine. Previous studies in people with CKD have shown that treatment with aspirin to help prevent heart disease may result in one extra serious bleeding episode per 500 people treated each year. The most serious possible side-effect is bleeding into the brain. This is rare, with 1-2 bleeds seen for every 10,000 people in the general population who are taking aspirin each year.

Where is the study run from?
The University of Southampton (UK) and 3 other UK universities

When is the study starting and how long is it expected to run for?
January 2018 to June 2025

Who is funding the study?
1. National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (UK)
2. The British Heart Foundation (UK)

Who is the main contact?
ATTACK study team
attack@nottingham.ac.uk

Study website
http://www.soton.ac.uk/attack-trial

Contact information

Type(s)
Public

Contact name
Dr . ATTACK study team

Contact details
Nottingham Clinical Trials Unit
University of Nottingham
Applied Health Research Building
University Park
Nottingham

United Kingdom
NG7 2RD
+44 (0)1158231451
attack@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number
2018-000644-26

IRAS number
228831

ClinicalTrials.gov number
NCT03796156

Secondary identifying numbers
31844

Study information

Scientific Title
ATTACK: Aspirin To Target Arterial events in Chronic Kidney disease

Acronym
ATTACK

Study objectives
The research aims to demonstrate whether the addition of low-dose (75 mg non-enteric coated) aspirin to usual care reduces the risk of major vascular events (excluding confirmed intracranial haemorrhage) in people with chronic kidney disease (CKD) who do not have pre-existing cardiovascular disease (CVD), and whether and to what extent the benefits outweigh any harms due to an increased risk of bleeding.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 21/09/2018, UK Medicines and Healthcare products Regulatory Agency (MHRA), ref: 16730/0223/001-0001
2. Approved 09/10/2018, East Midlands - Leicester Central Research Ethics Committee (REC), ref: 18/EM/0248
3. Approved 15/10/2018, Health Research Authority (HRA) and Health and Care Research Wales (HCRW)

Study design
Interventional pragmatic multi-centre open-label randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
https://www.southampton.ac.uk/attack-trial/information-for-patients.page

Health condition(s) or problem(s) studied
Chronic kidney disease (Stages 1-4)

Interventions
Current interventions as of 11/01/2021:

Eligible participants, based on prior results of blood and urine tests, will be randomised (open label randomisation) 1:1 to general practitioner (GP) prescription of aspirin (treatment arm 1) vs no prescription (and avoidance of aspirin) (treatment arm 2), stratified by age, diabetes and chronic kidney disease (CKD) severity.
Treatment arm 1 will receive 75 mg aspirin (non-enteric coated) to be taken daily, whereas treatment arm 2 will receive no aspirin and will be asked to avoid aspirin.
Participants will take the study medication for between 2.5 and 6 years, depending on when they are enrolled into the study. Follow-up will be until 1827 endpoints have occurred (this is anticipated 6 years after the recruitment start date, or 2.5 years following the recruitment end date).

Previous interventions:

Eligible participants, based on results of blood and urine tests taken at screening, will be randomised (open label randomisation) 1:1 to general practitioner (GP) prescription of aspirin (treatment arm 1) vs no prescription (and avoidance of aspirin) (treatment arm 2), stratified by age, diabetes and chronic kidney disease (CKD) severity.
Treatment arm 1 will receive 75 mg aspirin (non-enteric coated) to be taken daily, whereas treatment arm 2 will receive no aspirin and will be asked to avoid aspirin.
Participants will take the study medication for between 2.5 and 6 years, depending on when they are enrolled into the study. Follow-up will be until 1827 endpoints have occurred (this is anticipated 6 years after the recruitment start date, or 2.5 years following the recruitment end date).

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Aspirin

Primary outcome measure

Current primary outcome measure as of 12/05/2021:

Time to first major vascular event from the date of randomisation. A major vascular event is defined as a primary composite outcome of non-fatal myocardial infarction, non-fatal stroke and cardiovascular deathdeath (excluding confirmed intracranial haemorrhage and other fatal cardiovascular haemorrhage).

Previous primary outcome measure:
Time to first major vascular event from the date of randomisation. A major vascular event is defined as a primary composite outcome of non-fatal myocardial infarction, non-fatal stroke and cardiovascular death (excluding confirmed intracranial haemorrhage). Deaths from other causes (including fatal bleeding) will be treated as competing events. Patients who do not experience a major vascular event will be censored at the date of last follow-up.

Secondary outcome measures

Current secondary outcome measures as of 12/05/2021:

Secondary and tertiary outcome measures will be ascertained from four data sources (unless otherwise stated):
1. Office for National Statistics for mortality and cancer registration
2. Hospital Episode Statistics for hospital admissions
3. General practice Electronic Patient Record for coded cardiovascular episodes, bleeding episodes, coded diagnoses of dementia, recorded eGFR, and prescription of aspirin and other relevant medications
4. Self-reported information (including that from an annual patient questionnaire)
The four sources of data will be cross-referenced in order to build up a potential event record. Potential cardiovascular and major bleeding events will be formally adjudicated by an Endpoint Adjudication Committee.

The secondary outcome measures are the time to the following events from the baseline (except 1.4):
1. Efficacy:
1.1. Death from any cause
1.2. Composite outcome of major vascular event or revascularisation (coronary and non-coronary)
1.3. Individual components of the primary composite endpoint
1.4. Health-related quality of life, assessed using the EQ-5D-5L at the baseline and annually thereafter
2. Safety:
2.1. Composite outcome of intracranial haemorrhage (fatal and non-fatal), fatal extracranial haemorrhage and non-fatal major extracranial haemorrhage (adjudicated)
2.2. Fatal and non-fatal (reported individually and as a composite) intracranial haemorrhage comprising:
2.2.1. Primary haemorrhagic stroke (to distinguish from haemorrhagic transformation of ischaemic stroke)
2.2.2. Other intracranial haemorrhage (adjudicated). Intracranial haemorrhage will be sub-categorised as traumatic or non-traumatic.
2.3. Fatal and non-fatal (reported individually and as a composite) major extracranial haemorrhage:
2.3.1. Upper gastrointestinal

2.3.2. Lower gastrointestinal
2.3.3. Sight-threatening ocular
2.3.4. Multiple trauma
2.3.5. Other (adjudicated)
2.4. Clinically relevant non-major bleeding (if hospitalised) (adjudicated)
2.5. Composite outcome of fatal and non-fatal major extracranial haemorrhage and clinically relevant non-major bleeding (if hospitalised)

Tertiary (exploratory) outcome measures (all measures are the time to the following events from the baseline except hospitalizations):
1. Transient ischaemic attack
2. Unplanned hospitalisation
3. Hospitalisation with heart failure
4. New diagnosis of cancer (colorectal/other)
5. Death due to cancer (where cancer is underlying cause of death)
6. CKD progression
7. New diagnosis of dementia
8. Major non-traumatic lower limb amputation

Previous secondary outcome measures:
Secondary outcome measures will be ascertained from four data sources (unless otherwise stated):
1. Office for National Statistics for mortality and cancer registration
2. Hospital Episode Statistics for hospital admissions
3. General practice Electronic Patient Record for coded cardiovascular episodes, bleeding episodes, coded diagnoses of dementia, recorded eGFR, and prescription of aspirin and other relevant medications
4. Self-reported information (including that from an annual patient questionnaire)
The four sources of data will be cross-referenced in order to build up a potential event record. Potential cardiovascular and major bleeding events will be formally adjudicated by an Endpoint Adjudication Committee.
The secondary outcome measures are the time to the following events from the baseline (except 1.4):
1. Efficacy:
1.1. Death from any cause
1.2. Composite outcome of major vascular event or revascularisation (coronary and non-coronary)
1.3. Individual components of the primary composite endpoint (non-fatal myocardial infarction, non-fatal stroke and cardiovascular death (excluding confirmed intracranial haemorrhage))
1.4. Health-related quality of life, assessed using the EQ-5D-5L at the baseline and annually thereafter
2. Safety:
2.1. Composite outcome of intracranial haemorrhage (fatal and non-fatal), fatal extracranial haemorrhage and non-fatal major extracranial haemorrhage (adjudicated)
2.2. Fatal and non-fatal (reported individually and as a composite) intracranial haemorrhage comprising:
2.2.1. Primary haemorrhagic stroke (to distinguish from haemorrhagic transformation of ischaemic stroke): a) intracerebral and b) subarachnoid haemorrhage (reported individually and a composite) (adjudicated)
2.2.2. Other intracranial haemorrhage (subdural andextradural haemorrhage (reported as a composite) (adjudicated))
2.3. Fatal and non-fatal (reported individually and as a composite) major extracranial

haemorrhage:
2.3.1. Vascular-procedural
2.3.2. Vascular-non-procedural
2.3.3. Gastrointestinal
2.3.4. Genitourinary
2.3.5. Respiratory
2.3.6. Pericardial
2.3.7. Ocular
2.3.8. Other
2.3.9. Undetermined (adjudicated)
2.4. Clinically relevant non-major bleeding (adjudicated if hospitalised)

Overall study start date
01/01/2018

Completion date
30/06/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 20/03/2024:

1. Males and females aged 18 years and over at the date of screening
2. Subjects with CKD (reduced eGFR and/or albuminuria) defined as:
2.1. Estimated glomerular filtration rate [eGFR] <60mL/min/1.73m2 for at least 90 days, and/or
2.2. Kidney disease code on the GP electronic patient AND most recent eGFR in CKD-defining range (<60mL/min/1.73m2), and/or
2.3. Albuminuria or proteinuria (defined as urine albumin:creatinine ratio [ACR] ≥3mg/mmol, and /or urine protein:creatinine ratio [PCR] ≥15mg/mmol, and/or +protein or greater on reagent strip)
3. Subjects who are willing to give permission for their paper and electronic medical records to be accessed by trial investigators
4. Subjects who are willing to be contacted and interviewed by trial investigators
5. Subjects who can communicate well with the investigator or designee, understand the requirements of the study and understand and sign the written informed consent

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Previous inclusion criteria as of 11/01/2021:

1. Aged 18 years or over at the date of screening
2. Subjects with CKD, defined by at least one of the following:
2.1. Decreased estimated glomerular filtration rate [eGFR] for at least 90 days (defined as eGFR <60mL/min/1.73m2), and/or
2.2. Albuminuria or (where there are no measurements of albuminuria) proteinuria for at least 90 days (defined as urine albumin:creatinine ratio [ACR] ≥3mg/mmol, and/or urine protein: creatinine ratio [PCR] ≥15mg/mmol , and/or +protein or greater on reagent strip [and in all cases where the most recent qualifying result is ACR ≥3mg/mmol or PCR ≥15mg/mmol]), and/or
2.3. CKD formally diagnosed/coded on the GP electronic patient AND most recent quantitative tests within last 15 months and in CKD-defining range (eGFR <60mL/min/1.73m2 and/or ACR

≥3mg/mmol, and/or PCR ≥15mg/mmol)
3. Willing to give permission for their paper and electronic medical records to be accessed and abstracted by trial investigators for the duration of the trial
4. Willing to be contacted and interviewed by trial investigators should the need arise for adverse event assessment
5. Able to communicate well with the investigator or designee, to understand and comply with the requirements of the study and to understand and sign the written informed consent

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Previous participant inclusion criteria as of 08/01/2021:

1. Aged 18 years or over at the date of screening
2. Diagnosed with CKD, defined by at least one of the following:
2.1. Decreased estimated glomerular filtration rate (eGFR) for at least 90 days (defined as eGFR <60 ml/min/1.73m²)
2.2. Albuminuria or, where there are no measurements of albuminuria, proteinuria for at least 90 days (defined as the most recent qualifying result is ACR ≥3 mg/mmol or PCR ≥15 mg/mmol, and at least one of the following: urine albumin:creatinine ratio [ACR] ≥3 mg/mmol, and/or urine protein:creatinine ratio [PCR] ≥15 mg/mmol, and/or + protein or greater on reagent strip)
2.3. CKD formally diagnosed/coded on the GP electronic patient and most recent quantitative tests within the last 15 months in CKD-defining range (eGFR <60 ml/min/1.73m² and/or ACR ≥3 mg/mmol, and/or PCR ≥15 mg/mmol)
3. Willing to give permission for their paper and electronic medical records to be accessed and abstracted by trial investigators for the duration of the trial
4. Willing to be contacted and interviewed by trial investigators should the need arise for adverse event assessment
5. Able to communicate well with the investigator or designee, to understand and comply with the requirements of the study and to understand and sign the written informed consent

Previous participant inclusion criteria:

1. Aged 18 years or over at the date of screening
2. Diagnosed with CKD, defined by at least one of the following:
2.1. Estimated GFR <60 mL/min/1.73m² using Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) eGFR (at least two test results with eGFR <60 mL/min/1.73m² at least 90 days apart with no values ≥60 mL/min/1.73m² in the intervening period)
and/or:
2.2. Albumin-to-creatinine ratio (ACR) ≥3 mg/mmol (at least two test results in this range at least 90 days apart with no values <3 mg/mmol in the intervening period). Where no historical (within the last 4 years) results of ACR are available, patients with a screening ACR ≥3 mg/mmol who have a protein-to-creatinine ratio (PCR) ≥15 mg/mmol at least 90 days before with no values of PCR <15 mg/mmol in the intervening period will be eligible. Where there are no historical (within the last four years) ACR or PCR results, patients with a screening ACR ≥3 mg/mmol who have +protein or greater on a reagent strip at least 90 days before with no reagent strip results showing negative or trace protein in the intervening period will be eligible
3. Willing to give permission for their paper and electronic medical records to be accessed and abstracted by trial investigators for the duration of the trial
4. Willing to be contacted and interviewed by trial investigators should the need arise for adverse event assessment
5. Able to communicate well with the investigator or designee, to understand and comply with the requirements of the study and to understand and sign the written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25,210

Total final enrolment
4633

Key exclusion criteria
Current exclusion criteria as of 20/03/2024:

1. CKD GFR category 5
2. Pre-existing CVD:
2.1. Angina
2.2. Myocardial infarction
2.3. Stroke (ischaemic and haemorrhagic (intracerebral/subarachnoid))
2.4. Transient ischemic attack
2.5. Significant peripheral vascular disease
2.6. Coronary or peripheral revascularisation for atherosclerotic disease
3. Pre-existing condition associated with increased risk of bleeding other than CKD:
4. Subjects currently prescribed anticoagulants or antiplatelet agent, or taking over the counter (OTC) aspirin continuously
5. Currently and regularly taking other drugs with a potentially serious interaction with aspirin
6. Known allergy to aspirin or definite previous clinically important adverse reaction to aspirin
7. Poorly controlled hypertension (latest recorded systolic blood pressure ≥180 mmHg and/or diastolic blood pressure ≥105 mmHg)
8. Subjects with other conditions which in the opinion of their General Practitioner (GP) would preclude prescription of aspirin in routine clinical practice such as significant anaemia or thrombocytopenia
9. Pregnant or likely to become pregnant during the study period
10. Malignancy that is life-threatening or likely to limit prognosis, other life-threatening co-morbidity, or terminal illness
11. Behaviour or lifestyle would render them less likely to comply with study medication
13. In prison
14. Currently participating in another interventional clinical trial or who have taken part in a trial in the last 3 months

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Previous participant exclusion criteria as of 08/01/2021:

1. CKD GFR category 5
2. Pre-existing CVD:
2.1. Angina
2.2. Myocardial infarction
2.3. Stroke (ischaemic and haemorrhagic (intracerebral/subarachnoid))
2.4. Transient ischemic attack
2.5. Significant peripheral vascular disease
2.6. Coronary or peripheral revascularisation for atherosclerotic disease
Aortic aneurysm is not an exclusion criterion
3. Pre-existing condition associated with increased risk of bleeding other than CKD:
3.1. Upper GI bleed or peptic ulcer in the previous 5 years
3.2. Lower GI bleed in previous 12 months
3.3. Active chronic liver disease (such as cirrhosis)
3.4. Bleeding diathesis (investigator opinion)
4. Taking over the counter aspirin continuously
5. Currently prescribed anticoagulant or antiplatelet agents, including:
5.1. Acenocoumarol, phenindione, warfarin
5.2. Pixaban, edoxaban, rivaroxaban
5.3. Argatroban, bivalirudin, dabigatran
5.4. Aspirin, cangrelor, selexipag, cilostazol, clopidogrel, dipyridamole, prasugrel, ticagrelor, abciximab, eptifibatide, tirofiban, epoprostenol, iloprost
5.5. Unfractionated heparin, dalteparin, enoxaparin, tinzaparin
5.6. Danaparoid, fondaparinux
6. Currently and regularly taking other drugs with a potentially serious interaction with low-dose aspirin, including:
6.1. Non-steroidal anti-inflammatories (except topical preparations), including aceclofenac, acemetacin, celecoxib, dexibuprofen, dexketoprofen, diclofenac (and combination diclofenac-misoprostol preparation), etodolac, etoricoxib, felbinac, fenoprofen, flurbiprofen, ibuprofen, indometacin, ketoprofen, ketorolac trometamol, mefenamic acid, meloxicam, nabumetone, naproxen (and naproxen-esomeprazol), parecoxib, phenylbutazone, piroxicam, sulindac, tenoxicam, tiaprofenic acid, tolfenamic acid
6.2. Selective serotonin re-uptake inhibitors:citalopram, dapoxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline
6.3. Serotonin and noradrenaline re-uptake inhibitors: duloxetine, venlafaxine
6.4. Nicorandil
7. Known allergy to aspirin or definite previous clinically important adverse reaction to aspirin
8. Poorly controlled hypertension (latest recorded systolic blood pressure ≥180 mmHg and/or diastolic blood pressure ≥105 mmHg)
9. Subjects with other conditions which in the opinion of their General Practitioner (GP) would preclude prescription of aspirin in routine clinical practice such as significant anaemia or thrombocytopenia
10. Pregnant or likely to become pregnant during the study period
11. Malignancy that is life-threatening or likely to limit prognosis, other life-threatening co-morbidity, or terminal illness
12. Behaviour or lifestyle would render them less likely to comply with study medication (e.g. alcoholism, substance abuse, debilitating psychiatric conditions or inability to provide informed consent)
13. In prison
14. Currently participating in another interventional clinical trial or who have taken part in a trial in the last 3 months

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Previous participant exclusion criteria:

1. CKD GFR category 5
2. Pre-existing CVD:
2.1. Angina
2.2. Myocardial infarction
2.3. Stroke (ischaemic and haemorrhagic (intracerebral/subarachnoid))
2.4. Transient ischemic attack
2.5. Significant peripheral vascular disease
2.6. Coronary or peripheral revascularisation for atherosclerotic disease
Aortic aneurysm is not an exclusion criterion
3. Pre-existing condition associated with increased risk of bleeding other than CKD:
3.1. Upper GI bleed or peptic ulcer in the previous 5 years
3.2. Lower GI bleed in previous 12 months
3.3. Active chronic liver disease (such as cirrhosis)
3.4. Bleeding diathesis (investigator opinion)
4. Taking over the counter aspirin continuously
5. Currently prescribed anticoagulant or antiplatelet agents, including:
5.1. Acenocoumarol, phenindione, warfarin
5.2. Pixaban, edoxaban, rivaroxaban
5.3. Argatroban, bivalirudin, dabigatran
5.4. Aspirin, cangrelor, selexipag, cilostazol, clopidogrel, dipyridamole, prasugrel, ticagrelor, abciximab, eptifibatide, tirofiban, epoprostenol, iloprost
5.5. Unfractionated heparin, dalteparin, enoxaparin, tinzaparin
5.6. Danaparoid, fondaparinux
6. Currently and regularly taking other drugs with a potentially serious interaction with low-dose aspirin, including:
6.1. Non-steroidal anti-inflammatories (except topical preparations), including aceclofenac, acemetacin, celecoxib, dexibuprofen, dexketoprofen, diclofenac (and combination diclofenac-misoprostol preparation), etodolac, etoricoxib, felbinac, fenoprofen, flurbiprofen, ibuprofen, indometacin, ketoprofen, ketorolac trometamol, mefenamic acid, meloxicam, nabumetone, naproxen (and naproxen-esomeprazol), parecoxib, phenylbutazone, piroxicam, sulindac, tenoxicam, tiaprofenic acid, tolfenamic acid
6.2. Selective serotonin re-uptake inhibitors:citalopram, dapoxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline
6.3. Serotonin and noradrenaline re-uptake inhibitors: duloxetine, venlafaxine
6.4. Nicorandil
7. Known allergy to aspirin or definite previous clinically important adverse reaction to aspirin
8. Poorly controlled hypertension, defined as average of three readings at screening visit of systolic blood pressure ≥180 mm Hg and/or diastolic blood pressure ≥105 mm Hg
9. Anaemia (Hb <90 g/L or Hb <100 g/L with MCV ≤75 fL)
10. Pregnant or likely to become pregnant during the study period
11. Malignancy that is life-threatening or likely to limit prognosis, other life-threatening co-morbidity, or terminal illness
12. Behaviour or lifestyle would render them less likely to comply with study medication (e.g. alcoholism, substance abuse, debilitating psychiatric conditions or inability to provide informed consent)
13. In prison
14. Currently participating in another interventional clinical trial or who have taken part in a trial in the last 3 months

Date of first enrolment
22/10/2018

Date of final enrolment
21/12/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Southampton
Department of Population Health Sciences
Southampton
United Kingdom
SO16 6YD

Study participating centre
University of Nottingham
Nottingham Clinical Trials Unit
Nottingham
United Kingdom
NG7 2RD

Sponsor information

Organisation
University of Southampton

Sponsor details
University of Southampton
Research and Innovation Services
Southampton
England
United Kingdom
SO17 1BJ

Sponsor type
University/education

ROR
https://ror.org/01ryk1543

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

Funder Name
British Heart Foundation

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study results will be published in a scientific journal and at scientific meetings.

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
Requests for controlled access to the datasets generated and/or analysed during this study will be considered by the Sponsor, taking into consideration all legal and regulatory requirements. Where requests are approved, individual participant data will be shared after de-identification and normalisation of information (text, tables, figures, and appendices).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V3.1	23/10/2020	08/06/2021	No	No
Protocol article		21/04/2022	25/04/2022	Yes	No
HRA research summary			26/07/2023	No	No
Protocol file	version 5.0	12/05/2023	20/03/2024	No	No
Protocol file	version 5.1	18/06/2024	01/05/2025	No	No
Protocol file	version 5.2	27/02/2025	01/05/2025	No	No