ISRCTN17730734 https://doi.org/10.1186/ISRCTN17730734

A trial to investigate whether a heart pump improves the safety and effectiveness of high-risk coronary artery stenting procedures

Submission date
28/10/2020

Recruitment status
No longer recruiting

Registration date
30/10/2020

Overall study status
Ongoing

Last Edited
10/04/2026

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Over 100,000 coronary stent procedures, where small balloons are used to stretch open a narrowed blood vessel, are performed every year in the UK to treat people who have conditions such as angina or have suffered a heart attack.

For most patients the risk of complications is low, but for some, there is a higher risk of their heart failing during the procedure. Heart failure is a serious complication which can need treatment with a life support machine and lead to major damage to the heart muscle or even death. These risks are greatest in patients with severely diseased heart arteries and those who already have weakened heart muscle.

A new technology may be able to help with this problem. It consists of a small heart pump which is placed in the heart's main pumping chamber (the left ventricle, LV). This pump is known as a LV unloading device. The LV unloading device is inserted into the heart through a blood vessel in the leg and supports the heart muscle. It is removed at the end of the procedure or when the heart can pump safely on its own. Whilst this heart pump is promising, it comes with some risks of its own. These include bleeding and damage to the arteries in the legs. It is also expensive, costing £8,000 per operation. Currently, there is no strong evidence to guide the use of this device.

The CHIP study aims to determine whether these heart pumps are beneficial and cost-effective in patients receiving a stenting procedure who are at high-risk of complications.

Who can participate?
This study is open to patients who are due to receive a Percutaneous Coronary Intervention (PCI), or stenting, to treat narrow arteries in their heart and whose doctor believes they are at high-risk of complications.

What does the study involve?
If a patient chooses to participate in the CHIP trial and provides informed consent, they will be

randomly assigned to either the intervention or control arm. If they are assigned to the intervention arm, they will receive an LV unloading device with their stenting procedure. If they are assigned to the control arm, they will receive their stenting procedure as normal without the LV unloading device.

Before their procedure, participants will have a blood tests and be asked questions about their medical history. Patients will have heart scan, known as an ECG. These extra tests are to measure how well the patient's heart functions. Patients will also be asked to fill in 2 health questionnaires which will take around 20 mins and they can ask the nurse for help.

Following the procedure, participants will be contacted by a member of the research team 90 days and every year after their PCI, and at the end of the study. Participants will be asked to fill out two health questionnaires. GP and hospital records will be used to monitor the participant's health over the next 10 years following their enrolment in the trial.

What are the possible benefits and risks of participating?
There are a few potential risks that it is important to be aware of in this study. Participants who are randomised to the intervention arm will receive the LV unloading device. The device is passed into the heart on a thin catheter, this may cause bleeding, damage to the blood vessel or haemolysis. This happens in 1 in 20 cases. More major complications, such as severe bleeding, damage to the blood vessels which needs surgery, a stroke, damage to the heart or death, happens in less than 1 in 100 procedures. Additionally, as an X-ray is needed to help position the LV device, taking part in this study could involve an extra radiation dose of which can potentially be harmful. It is important to note that everyone in the study will have a PCI procedure, the risk and benefits of PCI will be discussed with you by your doctor. Any extra risk only affects those who have the LV unloading treatment.

As it is not known whether LV unloading is helpful it cannot be said whether or not there will be a direct benefit to participants. The information that is obtained when people take part in this study is likely to improve the treatment of people living with heart disease in the future.

Where is the study run from?
This study is run by King's College London (UK) and Guy's and St Thomas' Hospital NHS Foundation Trust (UK) in collaboration with the London School of Hygiene and Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?
From July 2020 to June 2026

Who is funding the study?
The National Institute of Health Research (NIHR) Health Technology Assessment (UK)

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT05003817

Integrated Research Application System (IRAS)
290599

National Institute for Health and Care Research (NIHR)
130593

Study information

Scientific Title
Controlled trial of High-risk coronary Intervention with Percutaneous left ventricular unloading (CHIP)

Acronym
CHIP-BCIS3

Study objectives
In patients undergoing high-risk percutaneous coronary intervention, a strategy of percutaneous left ventricular unloading is superior to standard care in terms of patient outcomes, quality of life and cost-effectiveness.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/05/2021, London - Bloomsbury Research Ethics Committee (HRA RES Centre Manchester, 3rd Floor Barlow House, 4 Minshull Street, Manchester M1 3DZ; bloomsbury.rec@hra.nhs.uk; +44 (0)207 104 8063), ref: 21/LO/0287

Study design
Multicentre open-label randomized controlled superiority trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ischaemic heart failure

Interventions

Participants will be randomized on a 1:1 basis prior to the PCI procedure using an electronic randomisation service.

Participants in the elective unloading (intervention) group will have a percutaneous left ventricular unloading device (pLVAD) inserted at the start of the procedure, before the coronary intervention. Maximal support will be provided throughout the procedure, following which support will be weaned and the device removed should the patient remain haemodynamically stable.

Participants in the control arm will receive the planned high-risk percutaneous coronary intervention as is the current standard of care without elective left ventricular unloading. Alternative mechanical circulatory support devices (such as the intra-aortic balloon pump (IABP) or extracorporeal membrane oxygenation (ECMO) will only be permitted in case of complications.

Intervention Type
Device

Phase
Phase III

Drug/device/biological/vaccine name(s)
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Primary outcome(s)
Current primary outcome measures as of 29/10/2025:
Composite hierarchical outcome of death, stroke, spontaneous myocardial infarction, cardiovascular hospitalisation (including prolongation of the index admission for bleeding and vascular complications) and periprocedural myocardial infarction analysed using a Win Ratio method between 12 and 51 months.

Previous primary outcome measures:
Composite hierarchical outcome of death, stroke, spontaneous myocardial infarction, cardiovascular hospitalisation (including prolongation of the index admission for bleeding and vascular complications) and periprocedural myocardial infarction analysed using a Win Ratio method between 1 and 4 years.

Key secondary outcome(s))
Current secondary outcome measures as of 05/02/2026:
1. Individual components of the primary outcome (as well as repeated occurrences of these events) between 12 and 51 months (including all-cause death, cardiovascular death, disabling stroke, spontaneous myocardial infarction, cardiovascular hospitalisation, periprocedural myocardial injury)
2. Completeness of revascularisation measured by the change in anatomic BCIS-JS and anatomic SYNTAX score between baseline and the completion of the final planned PCI procedure
3. Major bleeding defined using Bleeding Academic Research Consortium (BARC 3 to 5) classification at each timepoint post-randomisation
4. Vascular complication measured using VARC criteria at discharge from each planned PCI procedure
5. Procedural complication measured as the incidence of VT/VF requiring defibrillation, cardiorespiratory arrest, acute pulmonary oedema requiring assisted ventilation or prolonged

hypotension at discharge from each planned PCI procedure
6. Unplanned revascularisation at each timepoint post-randomisation
7. Health-related quality of life/functional status measured by the EuroQol 5-Dimension 5-level questionnaire (EQ-5D- 5L) at 90 days, 1 year and annually post-randomisation
8. Resource utilisation and cost effectiveness measured by incremental costs, quality-adjusted life years (QALYs) and net monetary benefit at 12 months
9. Acute kidney injury at 90 days post-randomisation, defined as prolongation hospital admission or readmission ≥24 hours with rise in creatinine to 200% of baseline value or need for new renal replacement therapy within 30 days of procedure.
10. Serial cardiac troponin (T or I) levels measured by immunoassay at baseline, 6 and 24 hours post-procedure
11. Length of stay measured by the duration of complete days following the index PCI procedure and any subsequent planned staged PCI procedure

Previous secondary outcome measures as of 29/10/2025:
1. Individual components of the primary outcome (as well as repeated occurrences of these events) between 12 and 51 months
2. Completeness of revascularisation measured by the change in anatomic BCIS-JS and anatomic SYNTAX score between baseline and the completion of the final planned PCI procedure
3. Major bleeding defined using Bleeding Academic Research Consortium (BARC 3 to 5) classification at each timepoint post-randomisation
4. Vascular complication measured using VARC criteria at discharge from each planned PCI procedure
5. Procedural complication measured as the incidence of VT/VF requiring defibrillation, cardiorespiratory arrest, acute pulmonary oedema requiring assisted ventilation or prolonged hypotension at discharge from each planned PCI procedure
6. Unplanned revascularisation at each timepoint post-randomisation
7. Health-related quality of life/functional status measured by the EuroQol 5-Dimension 5-level questionnaire (EQ-5D- 5L) at 90 days, 1 year and annually post-randomisation
8. Resource utilisation and cost effectiveness measured by incremental costs, quality-adjusted life years (QALYs) and net monetary benefit at 12 months

Previous secondary outcome measures as of 21/07/2021:
1. Individual components of the primary outcome (as well as repeated occurrences of these events) between 1 and 4 years
2. Completeness of revascularisation measured by the change in anatomic BCIS-JS and anatomic SYNTAX score between baseline and the completion of the final planned PCI procedure
3. Major bleeding (BARC 3 or 5) using the BARC classification up to 90 days post-randomisation
4. Vascular complication measured as the incidence of injury to a major artery or vein resulting in either major bleeding, tissue ischaemia/necrosis requiring percutaneous or surgical intervention, or death at discharge from each planned PCI procedure
5. Procedural complication measured as the incidence of VT/VF requiring defibrillation, cardiorespiratory arrest, acute pulmonary oedema requiring assisted ventilation or prolonged hypotension at discharge from each planned PCI procedure
6. Unplanned revascularisation up to 90 days post-randomisation
7. Health-related quality of life/functional status measured by the EuroQol 5-Dimension 5-level questionnaire (EQ-5D- 5L) at 90 days and 1 year
8. Resource utilisation and cost effectiveness measured by incremental costs, quality-adjusted life years (QALYs) and net monetary benefit at 12 months

Previous secondary outcome measures:
1. Individual components of the primary outcome (as well as repeated occurrences of these

events) between 1 and 4 years
2. Completeness of revascularisation measured by the change in anatomic BCIS-JS and anatomic SYNTAX score between baseline and the completion of the final planned PCI procedure
3. Major bleeding (BARC 3 or 5) using the BARC classification between baseline and 30 days after completion of the final planned PCI procedure
4. Vascular complication measured as the incidence of injury to a major artery or vein resulting in either major bleeding, tissue ischaemia/necrosis requiring percutaneous or surgical intervention, or death between baseline and 30 days after completion of the final planned PCI procedure
5. Procedural complication measured as the incidence of VT/VF requiring defibrillation, cardiorespiratory arrest, acute pulmonary oedema requiring assisted ventilation or prolonged hypotension between baseline and 30 days after completion of the final planned PCI procedure
6. Unplanned revascularisation between baseline and 30 days after completion of the final planned PCI procedure
7. Health-related quality of life/functional status measured by the EuroQol 5-Dimension 5-level questionnaire (EQ-5D-5L) at 30 days and 1 year
8. Resource utilisation and cost effectiveness measured by incremental costs, quality-adjusted life years (QALYs) and net monetary benefit at 12 months

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Extensive coronary disease defined by a British Cardiovascular Intervention Society (BCIS) Jeopardy Score ≥8
2. Severe left ventricular systolic dysfunction defined as an LVEF ≤35% (or ≤45% in the presence of severe mitral regurgitation)
3. Complex PCI defined by the presence of at least one of the following criteria:
3.1. Unprotected left main intervention in the presence of
3.1.1. An occluded dominant right coronary artery or
3.1.2. A left dominant circulation or
3.1.3. Disease involving the entire bifurcation (Medina 1,1,1 or 0,1,1)
4. Intended calcium modification (by rotational atherectomy, lithotripsy or laser)
4.1. In multiple vessels or
4.2. In the left mainstem or
4.3. In a final patent conduit or
4.4. Where the anatomic SYNTAX score is ≥32
5. Target vessel is a chronic total occlusion with a planned retrograde approach

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
300

Key exclusion criteria
Current exclusion criteria as of 23/02/2023:

1. Cardiogenic shock or acute STEMI at randomisation (including current treatment with a mechanical circulatory support device)
2. Contraindication to pLVAD insertion
3. Inability to give informed consent
4. Previously enrolled in CHIP or current enrolment in another interventional study that may affect CHIP outcomes

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Previous exclusion criteria:

1. Cardiogenic shock or acute STEMI at randomization
2. Contraindication to pLVAD insertion
3. Inability to give informed consent
4. Previously enrolled in CHIP or current enrolment in another interventional study that may affect CHIP outcomes

Date of first enrolment
06/08/2021

Date of final enrolment
03/12/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
London
England
SE1 7EH

Sponsor information

Organisation
King's College London

Organisation
Guy’s and St Thomas’s NHS Foundation Trust

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

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?
Results article		29/03/2026	10/04/2026	Yes	No
Protocol article		01/03/2024	24/07/2024	Yes	No
HRA research summary			26/07/2023	No	No
Protocol file	version 1.1	11/05/2021	13/08/2021	No	No
Protocol file	version 1.2	03/11/2022	03/02/2023	No	No

Protocol file	version 1.3	22/05/2023	24/11/2023	No	No
Protocol file	version 1.4	22/05/2024	24/07/2024	No	No
Study website		11/11/2025	11/11/2025	No	Yes