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	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 30/10/2020	**Overall study status** Ongoing	
Last Edited 03/12/2024	**Condition category** Circulatory System	

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 asked to come back to their Hospital to see a member of the research team 30 days and 12 months after their PCI. Participants will receive more blood tests and be asked to fill out 2 health questionnaires. There won't have any more hospital visits because of the study after this and participant's GP and Hospital records will be used to monitor their health up to 4 years following their enrollment 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?
1. Prof Divaka Perera, divaka.perera@kcl.ac.uk
2. Ms Megan Knight, chip-bcis3@LSHTM.ac.uk
3. Dr Matthew Ryan, matthew.ryan@kcl.ac.uk

Study website
https://www.lshtm.ac.uk/chip-bcis3

Contact information

Type(s)
Scientific

Contact name
Prof Divaka Perera

ORCID ID
http://orcid.org/0000-0001-6362-1291

Contact details
The Rayne Institute
King's College London
4th Floor Lambeth Wing
St Thomas Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH
+44 (0)2071881048
divaka.perera@kcl.ac.uk

Type(s)
Public

Contact name
Ms Megan Knight

Contact details
LSHTM
Keppel Street
London
United Kingdom
WC1E 7HT
+44 (0)20 7927 2723
chip-bcis3@LSHTM.ac.uk

Type(s)
Scientific

Contact name
Dr Matthew Ryan

ORCID ID
http://orcid.org/0000-0001-8256-195X

Contact details
The Rayne Institute
King's College London

4th Floor Lambeth Wing
St Thomas Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH
+44 (0)2071881048
matthew.ryan@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
290599

ClinicalTrials.gov number
NCT05003817

Secondary identifying numbers
IRAS 290599, HTA - NIHR130593

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet yet available

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)
-

Primary outcome measure
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

Secondary outcome measures
Current 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

Overall study start date
01/07/2020

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

Age group
Adult

Sex
Both

Target number of participants
300

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

———

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
01/07/2021

Date of final enrolment
03/12/2024

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
King's College London

Sponsor details
The Strand
London
England
United Kingdom
WC2R 2LS
+44 (0)20 7188 7188
R&D@gstt.nhs.uk

Sponsor type
University/education

Website
https://www.kcl.ac.uk/scms

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

Sponsor details
NIHR GSTFT/KCL Biomedical Research Centre
16th Floor, Tower Wing, Guy's Hospital
London
England
United Kingdom

SE1 9RT
+44 (0)20 7188 7188
R&D@gstt.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.guysandstthomas.nhs.uk/our-services/cardiovascular/overview.aspx

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
Results of the trial will be published in an academic journal and presented at international conferences. Participants will be provided with summaries of the results in lay language.

Intention to publish date
30/06/2025

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?
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
HRA research summary			26/07/2023	No	No
Protocol file	version 1.3	22/05/2023	24/11/2023	No	No
Protocol article		01/03/2024	24/07/2024	Yes	No
Protocol file	version 1.4	22/05/2024	24/07/2024	No	No