



**168**  
PATIENTS  
RECRUITED

Issue no.11 January 2024

## NEWS

We hope everyone had an enjoyable festive period. December was another great month for CHIP-BCIS3, with **11 patients** randomised.

In the last quarter (Q4 Oct - Dec) of 2023, we had our best months for recruitment since the start of the study, with a total of **39 patients** recruited across **17 sites!** (see below). Truly incredible work to you all!



An extra special mention to the these sites who recruited **at least one** participant **every month** from October to December 2023!



# WELCOME

We also welcome our **21st** recruiting site for the trial - a very warm welcome to **Royal Cornwall Hospital, Truro!** We are looking forward to working with you all.

# CHIP-BCIS3 Investigators' Breakfast Meeting and exhibition stand at BCIS ACI 2024

If you are attending the **BCIS ACI conference** at the London Hilton Metropole, we would like to invite you to the CHIP-BCIS3 Breakfast Meeting on **Thursday 1st February 2024** between **7:45-8:45am** in **Mezzanine 1-4**. Refreshments will be provided.

If you would like to attend, please get in touch with us as soon as possible.

We also have a stand in the exhibition hall during the conference, so please come and say hello in-between sessions!



## PROMOTIONAL MATERIAL

Recruitment is going really well and we want to keep up the momentum, so promoting the trial amongst your colleagues is more important than ever!

Many of you will already have our trial poster but if you would like more copies, or have not received one, please contact us using the details below. We can provide laminated or unlined posters in A4 and/or A3 sizes. These posters can be displayed in cath labs and MDT meeting rooms, but please don't display them in patient-facing areas as they aren't approved by ethics.

We have also created a trial Investigator's leaflet which we will have at our BCIS ACI stand and will be sending out to all sites very shortly. Please share amongst colleagues at your site.

**BACKGROUND**

PCI is the most common method used to treat coronary heart disease, but carrying a risk for complications. Percutaneous left ventricular LV unloading devices offer potential to reduce these complications, and are being used increasingly in the real world. However, there is currently a significant lack of robust evidence for their use and efficacy of pLVAD supported high-risk PCI compared to the current standard of care.

**AIM:** To establish whether, in patients undergoing high-risk PCI, a strategy of percutaneous LV unloading is superior to standard care in terms of patient outcomes, quality of life and cost-effectiveness.

**SCREENING**

All patients undergoing PCI should be screened for eligibility at the time of listing. They may come from the following sources:

- Patients referred to the Heart Team for consideration of revascularisation
- Patients seen to acquire criteria for consideration of PCI
- Patients referred for advanced imaging to plan complex revascularisation
- Patients currently admitted with acute coronary syndromes or acute heart failure, either at the site or planned for transfer from a referring centre
- Existing coronary angiography in patients who are known to have poor left LV function

Detailed screening screening logs of all patients with extensive CAD and EF < 35% considered for the trial will be completed at site.

**CONTACT US**

**EMAIL:** [CHIP-BCIS3@LSHTM.ac.uk](mailto:CHIP-BCIS3@LSHTM.ac.uk)

**TWITTER:** @CHIP\_BCIS3

**WEBSITE:** [www.lshtm.ac.uk/CHIP-BCIS3](http://www.lshtm.ac.uk/CHIP-BCIS3)

or talk to your local contact:

CHIP BCIS3 leaflet version 1, 14th January 2024

Did you know that there is **NO robust evidence for use of percutaneous LV unloading support when performing high-risk PCI?**

**INCLUSION CRITERIA**

- Extensive coronary disease defined by a British Cardiovascular Intervention Society (BCIS) severity Score ≥ 8\*
- Severe left ventricular systolic dysfunction defined as a LVEF ≤ 35% or a 45% in the presence of severe mitral regurgitation†
- Complex PCI defined by the presence of at least one of the following criteria:
  - Unprotected left main intervention in the presence of an occluded dominant right coronary artery or a left dominant circulation or
  - disease involving the entire bifurcation (Medina 1,1,1 or 0,1,1)
  - Intended calcium modification (by rotational or orbital atherectomy, ablation or laser)
  - in multiple vessels or
  - in the left mainstem or
  - in a final patient conduct or
  - where the anatomic SYNTAX score is ≥ 22
  - Target vessel is a chronic total occlusion with planned retrograde approach

\*In general, patients who do not have bypass grafts will be eligible if they have an occluded proximal left anterior descending (LAD) disease or at least proximal 2 vessel disease. For patients with patent bypass grafts, or in cases where the extent of coronary artery disease (CAD) is uncertain, the BCIS JS should be calculated. The maximum possible JS score is 22. NB: The JS should be based on all coronary disease, not just the vessel undergoing stent myocardium.

†Biplane/2D echocardiography or cardiac MRI can be used to assess the qualifying LVF.

**EXCLUSION CRITERIA**

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

**TRIAL FLOWCHART**

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    graph TD
      A[Randomise] --> B[Elective LV Unloading]
      A --> C[No LV Unloading]
      B --> D[PCI]
      C --> E[PCI]
      D --> F[Follow up (minimum duration: 30d) Primary Analysis: We Ratio of Intracardiac Compensatory Response]
      E --> F
    
```

**CASE STUDY**

Mrs C presented to her local hospital with a non-ST elevation myocardial infarction and was found to have severe left ventricular systolic dysfunction on echocardiography with an ejection fraction of 20%.

Coronary angiography revealed an occluded right coronary artery and severe left main stem disease. Her case was discussed in the heart team meeting and it was felt either surgical or percutaneous revascularisation were reasonable and following a joint consultation with a surgeon and interventional cardiologist Mrs C decided to proceed with percutaneous coronary intervention (PCI).

Inclusion criteria for CHIP-BCIS3 were met (Ejection Fraction < 35%, BCIS JS = 12 and left main stem intervention in the presence of an occluded right coronary), after being given information about the study Mrs C kindly agreed to participate in CHIP-BCIS3 and was randomised to the no LV unloading group.

**Performing high-risk PCI in patients with pLVAD (Impella) support?**

Did you know there is **NO robust evidence for use of pLVAD support in these patients?**

We are conducting the First Randomised Controlled Trial to assess pLVAD efficacy and long-term safety outcomes in the UK.

Help answer this important question, which will enable evidence-based treatment decisions to be made by patients and clinicians.

Contact the local research team:

NIHR

## CONTACT US



If you have any questions please don't hesitate to contact the CTU team - Matt Kwok, Megan Knight, Laura Van Dyck and Richard Evans.

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