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Evaluating the accuracy of remote monitoring technology in capturing how patients respond to treatments for pulmonary arterial hypertension

Submission date
18/03/2026

Recruitment status
No longer recruiting

Registration date
25/03/2026

Overall study status
Ongoing

Last Edited
10/04/2026

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Pulmonary arterial hypertension (PAH) is a serious condition caused by the narrowing and stiffening of the small blood vessels in the lungs. This makes it harder for the heart to pump blood, leading to breathlessness and tiredness. While there are several effective treatments, doctors currently have to rely on hospital-based tests, some of which are invasive, to see how well a treatment is working. This means it can take a long time to find the best drug for an individual patient.
The aim of this study is to see if small, implanted devices can accurately monitor a patient's health from their own home. We want to know if these devices can detect changes in lung pressure and heart function quickly after a patient starts or changes their medication. This could help doctors personalise treatment more effectively and reduce the need for hospital visits.

Who can participate?
Participants must be adults aged between 18 and 80 years who have been diagnosed with certain types of PAH. They should already be taking standard PAH medications but still have symptoms (known as World Health Organisation Functional Class III). Participants must be able to walk a minimum distance during a standard walking test. People who are pregnant or have certain other heart or lung conditions cannot take part.

What does the study involve?
All participants will have two small devices implanted:
1. CardioMEMS™: A tiny wireless sensor placed in the lung artery to measure blood pressure.
2. ConfirmRx™ (or similar): A small monitor placed under the skin of the chest to track heart rate and rhythm.
Participants are randomly assigned to a sequence of two different oral treatments (selexipag and riociguat). This is a cross-over study, meaning instead of one group getting Drug A and another group getting Drug B, every participant will have the opportunity to try both drugs at different times. This allows us to compare how the same person's body responds to each

treatment.
Throughout the study, the devices will send daily health data to the clinical team. Participants will also attend hospital visits for heart scans (MRI), walking tests, and blood tests, and will complete weekly questionnaires about their quality of life and any side effects.

What are the possible benefits and risks of participating?
Participants may benefit from closer monitoring of their condition and the opportunity to try different approved treatments to find what works best for them. The information gathered will also help improve care for other people with PAH in the future.
The risks include those associated with the minor surgical procedures to implant the devices, such as bruising, pain, or a small risk of infection or bleeding. There are also potential side effects from the medications used, which can include headaches, nausea, or jaw pain. The study team will monitor all participants closely for any problems.

Where is the study run from?
The study is managed by Sheffield Teaching Hospitals NHS Foundation Trust in collaboration with the University of Sheffield. Recruitment takes place at several specialist national pulmonary hypertension centres across the UK.

When is the study starting and how long is it expected to run for?
June 2023 to January 2027

Who is funding the study?
Medical Research Council (MRC) (UK)

Who is the main contact?
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT05825417

Integrated Research Application System (IRAS)
325120

Central Portfolio Management System (CPMS)
55838

Study information

Scientific Title
A multicentre randomised crossover trial of disease-specific therapy in patients with pulmonary arterial hypertension implanted with pulmonary artery pressure and cardiac rhythm monitoring devices (CardioMEMS/ConfirmRx)

Acronym
PHoenix

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/05/2025, North East - York Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8079; york.rec@hra.nhs.uk), ref: 23/NE/0067

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Crossover

Purpose
Device feasibility, Diagnostic, Health services research, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Pulmonary arterial hypertension (PAH)

Interventions
In this study, patients established on guideline-recommended therapy will be implanted with devices and remote monitoring established. Patients will then enter into a 2 x 2 crossover study of approved drugs during which standard clinical investigations will be undertaken at baseline and maximal therapy on each drug. The crossover design will provide multiple increases and decreases of drugs known to alter haemodynamics and 6MWT. The study is powered to detect improvement in right ventricular stroke volume measured by MRI from baseline to maximal therapy for each drug. It will then be established if changes in remote-monitored measures provide an early indication of clinical efficacy when compared to the MRI, haemodynamics, NTproBNP and 6MWT made at 12 weeks. Remote measurement of haemodynamics during the two periods of de-escalation will inform understanding of physiology and inform clinical practice. The comparison of the two therapeutic strategies in individual patients in one study will facilitate novel clinical study designs and provide evidence for data-driven personalised medicine in the area.

Participants will be randomised 1:1 to one of two treatment sequences (Arm A or Arm B) using a concealed, web-based randomisation system via the Zeesta eCRF portal. To ensure balanced groups across centers, a block randomisation method (block size of 4) stratified by study site will be used. Participants will undergo implantation of two monitoring devices: the CardioMEMS™ HF System (to monitor pulmonary artery pressure) and the Confirm Rx™ ICM (to monitor cardiac rhythm or equivalent device).

Treatment arms:
Arm A Treatment: Participants first receive selexipag (oral prostacyclin IP receptor agonist) added to their background therapy (PDE5i and ERA). This is followed by a "washout" period where they revert to baseline therapy before switching to riociguat (oral sGCS).
Arm B Treatment: Participants follow the reverse sequence, receiving riociguat (which requires withdrawal of their background PDE5i) followed by selexipag.

Method and frequency of administration
1. Selexipag (Uptravi): Administered as oral tablets twice daily, titrated from 200 mcg up to a maximum tolerated dose (max 1600 mcg) over the treatment period.
2. Riociguat (Adempas): Administered as oral tablets three times daily, titrated from 1 mg up to a maximum of 2.5 mg based on blood pressure.

Duration and follow-up:
Patients will complete two 12-week treatment periods (total 24 weeks) + reduce OPA and washout period. Clinical investigations (cardiac MRI, 6MWT, and NTproBNP) will be conducted at baseline and at the end of each 12-week maximal therapy period.

Monitoring: Remote hemodynamic data will be captured daily throughout the entire study duration to evaluate the device's efficacy in detecting physiological changes compared to standard clinical markers.

Intervention Type
Drug/Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Selexipag, riociguat, ConfirmRx, CardioMEMS

Primary outcome(s)
1. Right ventricular stroke volume (RVSV) measured using MRI at baseline to final visit (following the 8-week titration and 12-week stable dose period for each drug)

Key secondary outcome(s)
Remote monitoring (continuous daily data):
1. Haemodynamic parameters: continuous measurement of mean pulmonary artery pressure (mPAP), cardiac output (CO), cardiac index, and total pulmonary resistance (TPR) measured via the CardioMEMS™ device daily from baseline through to the final visit.
2. Heart rate metrics: daily heart rate (day/night) and heart rate reserve measured via the ConfirmRx™ cardiac monitor from baseline through to the final visit.
3. Physical activity: minutes of activity per day measured via the ConfirmRx™ device daily from baseline through to the final visit.

Clinical and functional assessments:
1. Field walk test performance: such as the incremental shuttle walk test (ISWT), 6-minute walk test (6MWT), or endurance shuttle walk test (ESWT) measured using watch at baseline and the final visit each arm.
2. WHO Functional Class: heart failure symptoms assessed using the World Health Organization (WHO) Functional Classification at baseline and the final visit of each arm.
3. Blood biomarkers: concentration of N-terminal B-type natriuretic peptide (NT-proBNP) measured via laboratory blood analysis at baseline and the final visit of each arm.
4. Cardiac MRI sub-measures: assessment of right ventricular ejection fraction (RVEF), right ventricular end-diastolic volume (RVEDV), and left ventricular volumes using MRI at baseline and the final visit of each arm.

Patient-reported outcome measures (PROMs):
1. Health-related quality of life: measured using the EmPHasis-10 questionnaire weekly from baseline through to the final visit of each arm.
2. Medication side effects: self-reported side effects captured through the PHoenix side-effects questionnaire at baseline and weekly throughout the dose titration and stable therapy periods of each arm.
3. Mental health screening: symptoms of anxiety and depression measured via Generalized Anxiety Disorder (GAD-2/7) and Patient Health Questionnaire (PHQ-2/9) at baseline and weekly through to the final visit of each arm.
4. Medication compliance: assessment of adherence through the PHoenix-PRO questionnaire at baseline and weekly through to the final visit of each arm.

Summary of assessment timepoints:
1. Continuous remote data: analysed as absolute change from baseline and area under the curve (AUC) at 4 weeks, 8 weeks, and 12 weeks on each therapy to determine the "time-to-effect".
2. Hospital visits: formal clinical assessments (MRI, Walk Tests, NT-proBNP) occur at baseline and upon reaching the maximal therapy dose (typically after 12 weeks of treatment per phase).

Completion date
31/01/2027

Eligibility

Key inclusion criteria
1. Able to provide informed consent
2. Age 18-80 years
3. PAH which is idiopathic, heritable or associated with drugs, toxins or connective tissue disease
4. Stable PAH therapeutic regime comprising any combination of ERA and PDE5i for at least 1 month prior to screening (unless unable to tolerate therapy)
5. WHO functional class III
6. Resting mean pulmonary arterial pressure (mPAP) ≥20 mmHg, pulmonary capillary wedge pressure ≤15 mmHg, pulmonary vascular resistance ≥2 Wood Units measured by right heart catheterisation at time of diagnosis
7. Six-minute walk test (6MWT) >50 m at entry
8. Estimated glomerular filtration rate (eGFR) >30 ml/min/1.73 m² at entry (Appendix C)
9. Inadequate treatment response (clinically determined)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
42

Key exclusion criteria
1. Unable to provide informed consent
2. Pregnancy
3. Unprovoked pulmonary embolism (at any time)
4. Acute infection at time of screening (rescreening is permitted)
5. PAH due to human immunodeficiency virus, portal hypertension, schistosomiasis, congenital heart disease

6. Pulmonary hypertension due to left heart, lung, thromboembolic or unclear/multifactorial disease (Group II-V)
7. Unable to tolerate aspirin or P2Y12 inhibitor
8. Hypersensitivity to selexipag or riociguat
9. Clinically significant renal disease (eGFR ≤30 ml/min/1.73 m2)
10. Anaemia (haemoglobin <10 g/dl)
11. Left-sided heart disease and/or clinically significant cardiac disease, including but not limited to any of the following: aortic or mitral valve disease greater than mild aortic insufficiency; mild aortic stenosis; mild mitral stenosis; or moderate mitral regurgitation

Date of first enrolment
13/06/2023

Date of final enrolment
13/03/2026

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Royal Hallamshire Hospital
Glossop Road
Sheffield
England
S10 2JF

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
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Study participating centre
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Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

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