ISRCTN13249878 https://doi.org/10.1186/ISRCTN13249878

Pace and diagnose in suspected cardiomyopathy

Submission date 06/10/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 14/11/2025	**Overall study status** Ongoing	
Last Edited 06/01/2026	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
The study aims to evaluate the technical feasibility and performance of lead-in-sheath endomyocardial (heart tissue) biopsy in possible cardiac sarcoidosis and cardiac amyloidosis.

Who can participate?
Adult patients >18 years of age undergoing Cardiac Implantable Electronic Device (CIED) implant, with clinically suspected cardiac sarcoidosis or amyloidosis

What does the study involve?
The study involves heart tissue biopsy using two methods. One method is the standard of care bioptome (tiny forceps), which takes a small sample of heart tissue during a pacemaker procedure. The second method is using a non-standard of care pacing lead to take a small sample of heart tissue. All samples will be sent to Royal Papworth Hospital for analysis and to try and identify a cause for the patient's heart disease.

What are the possible benefits and risks of participating?
The main benefit of the study is that, rather than just treating the patient’s abnormal heart rhythm or heart pump failure, it may actually identify an underlying cause of their heart disease. The conditions being investigated have specific treatments that can prevent disease progression and reduce the risk of life-threatening complications.

The first possible risk is the exposure to ionising radiation. But the IRMER guidelines ensure that radiation exposure is kept as low as reasonably practicable, safeguarding both patients and healthcare professionals. Another risk is temporary conduction disturbance (slow heart rhythms). These patients will be undergoing
pacemaker procedures, and therefore, the ability to provide temporary pacing is immediately available. In patients with signs of particular rhythm issues, which place them at higher risk of this occurring (‘left bundle branch block’ seen on the electrogram before starting), a pacemaker lead can be placed to provide support before taking biopsies. The final risk is pericardial bleed (bleeding in the space around the heart). Patients will be monitored closely for any signs of this during and after the procedure on the heart day case unit. If this were to occur, it can be treated by placing a drain from under the breastbone using ultrasound and local anaesthetic. Usually,

the leak seals itself in under 24 hours, and the drain is removed. In the procedure, biopsies will be guided by a long, thin tube or sheath onto the safest part of the heart to take samples, reducing the risk of causing a bleed.

Where is the study run from?
The Clinical Research Facility at University Hospital Sussex NHS Foundation Trust, UK.

When is the study starting and how long is it expected to run for?
July 2025 to July 2027. Recruitment is aimed to last 18 months with the patients having a 4-6 month follow up as per standard of care.

Who is funding the study?
The University Hospitals Sussex NHS Foundation Trust's internal My UHSx Doctoral Fellowships Programme, UK.

Who is the main contact?
john.hildred1@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Rebecca Godfrey

Contact details
University Hospital Sussex NHS Foundation Trust
Brighton
United Kingdom
BN2 5BE
+44 (0)1273696955
rebecca.godfrey@nhs.net

Type(s)
Principal investigator, Scientific, Public

Contact name
Dr John Silberbauer

Contact details
Sussex Cardiac Centre, Royal Sussex County Hospital, Eastern Road
Brighton
United Kingdom
BN2 5BE
+44 (0)1273 696955
john.silberbauer@nhs.net

Type(s)
Public

Contact name
Mr John Hildred

Contact details
University Hospital Sussex NHS Foundation Trust
Clinical Research Facility, 1 Abbey Road, Kemptown
Brighton
United Kingdom
BN2 5BE
+44 (0)1273 696955 ext 62756
john.hildred1@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
357728

ClinicalTrials.gov (NCT)
Nil known

Study information

Scientific Title
Lead-in-sheath endomyocardial biopsy: a prospective cohort study evaluating and advancing this technique in suspected cardiac sarcoidosis and amyloidosis

Study objectives
Primary:
- To evaluate the technical feasibility and performance of lead-in-sheath EMB in possible cardiac sarcoidosis and cardiac amyloidosis

Secondary:
- To compare the safety of concurrent EMB with standalone CIED implant
- To assess if performing EMB influences the working diagnosis or treatment plan for patients
- To correlate non-invasive cardiovascular magnetic resonance (CMR) scans, Electroanatomic Mapping (EAM), and pacing parameters (sensed unipolar electrogram, and paced ECG) with EMB findings to characterise location and depth

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/11/2025, South West – Cornwall and Plymouth REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; cornwallandplymouth.rec@hra.nhs.uk), ref: 25/SW/0144

Study design
Single-site proof-of-principle study

Primary study design
Interventional

Study type(s)
Diagnostic, Efficacy, Safety

Health condition(s) or problem(s) studied
Patients with suspected cardiac sarcoidosis and or cardiac amyloidosis

Interventions
Using a Bioptome to take an Endomyocardial Biopsy sample in patients suspected of having Cardiac Sarcoidosis or Cardiac Amyloidosis (Standard of Care)
Using a Lead in Sheath method for Endomyocardial Biopsy in patients with suspected cardiac sarcoidosis and cardiac amyloidosis (Non Standard of Care)

Intervention Type
Procedure/Surgery

Primary outcome(s)
Successful endomyocardial biopsy (EMB) using the lead-in-sheath method, defined as yielding myocardial tissue, measured during pathology analysis post procedure

Key secondary outcome(s))
1. Safe EMB, defined as no increase in adverse event rate, when compared with standalone CIED implant, measured by monitoring the adverse event rate at 4-6 months follow-up
2. Change in working diagnosis and treatment plan measured using patient clinical history and medication review following EMB at 4-6 month follow-up
3. Correlation of pacing parameters and multi-parametric non-invasive CMR imaging, and EAM (mapped voltage and frequency) abnormalities with EMB findings to characterise location and depth measured after the procedure

Completion date
01/12/2027

Eligibility

Key inclusion criteria
1. Patient undergoing Cardiac Implantable Electronic Device (CIED) implant, with clinically suspected cardiac sarcoidosis or amyloidosis
2. Indication for EMB

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Unable to give informed consent
2. Age <18
3. Pregnant or breastfeeding
4. Current participation in another interventional research study

Date of first enrolment
10/12/2025

Date of final enrolment
01/07/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals Sussex NHS Foundation Trust
Worthing Hospital
Lyndhurst Road
Worthing
England
BN11 2DH

Sponsor information

Organisation
University Hospitals Sussex NHS Foundation Trust

ROR

https://ror.org/03wvsyq85

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospitals Sussex NHS Foundation Trust

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?
Participant information sheet	version 3.0	04/12/2025	18/12/2025	No	Yes