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Building a realistic pacing simulator

Submission date 19/08/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 01/09/2021	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 09/10/2024	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
A pacemaker is a small electrical device used to treat some abnormal heart rhythms (arrhythmias) that can cause your heart to either beat too slowly or miss beats.
All patients at Harefield Hospital undergoing open-heart surgery have a temporary pacemaker inserted during the operation because electrical conduction disturbance is common.
Temporary pacing management can be complicated because certain parameters change quickly and failure to program the pacemaker settings accordingly can result in lower blood pressures or dangerous heart rhythms. Therefore, temporary pacemakers require daily checks.
However, there is limited standardised training in temporary pacemaker management in the UK and no simulator training.
Aims:
1. To create a pacing simulator to train doctors how best to manage and adjust temporary pacemakers
2. To build an automatic alarm system to detect poor pacemaker settings and clearly show how to adjust the settings correctly

Who can participate?
We will recruit patients at Harefield Hospital who are undergoing cardiac surgery for Coronary Artery Bypass Grafting (CABG) and/or Aortic, Mitral and Tricuspid Valve surgery. Patients with all levels of heart function (including those with normal heart function and severely impaired heart function) will be included as the aim is to build a simulator and correction algorithm that is applicable to a wide array of patients.

What does the study involve?
We will recruit 25 patients at Harefield Hospital who already have temporary pacemakers after cardiac surgery. We will then perform the usual safety checks on enrolled participants within 72 hours of surgery and modify the pacemaker settings to find the settings that achieve the highest blood pressure.
During the setting changes we will record a number of measurements. Blood pressure will be measured via an arterial line (a plastic tube inserted into an artery in the wrist that directly measures the blood pressure) and also via a device that measures blood pressure with a sensor placed on the fingertip. The electrical activity of the heart will be measured by electrodes placed on the surface of the chest, otherwise known as an electrocardiogram (ECG). A set of tubing inserted into one of the large veins in the neck will measure pressure in the veins. Finally,

ultrasound images of the heart (an echocardiogram) will also be taken during the setting changes to measure, amongst other things, how quickly blood is travelling in the heart using different settings.
The collection of data from each participant will take 1-2 hours. They will undergo no additional invasive procedures. The collection of data will take less than one year.
Once the data is collected, we will analyse the data using a variety of machine learning techniques to identify features that define the traces as safe vs unsafe and optimal or suboptimal. Once this data is collected it can be used to create the automatic detection algorithm and form the basis of the simulator.

What are the possible benefits and risks of participating?
Benefits: None
Risks: The only disadvantage is the time commitment during the data collection of one to two hours rather than the usual 15 minutes for a temporary pacemaker check. During the check we will also use the echocardiogram machine which uses ultrasound to take images of the heart from outside the chest wall.

Where is the study run from?
Harefield Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2020 to March 2023

Who is funding the study?
Royal Brompton and Harefield NHS Trust (UK)

Who is the main contact?
Dr Alexander Tindale, a.tindale@rbht.nhs.uk

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number
292373

ClinicalTrials.gov number

Secondary identifying numbers
CPMS 49062, IRAS 292373

Study information

Scientific Title
Building a high-fidelity temporary pacing simulator and automatic alerting tool

Acronym
PACESIM

Study objectives
1. By collecting and analysing data using machine learning techniques from patients with optimal and suboptimal pacing modes, I will build a simulator to train healthcare professionals to optimise pacing in individual patients
2. The same dataset can be used to create an algorithm that will allow automatic adjustments of temporary pacing outputs to optimise haemodynamic parameters

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/05/2021, South West - Cornwall & Plymouth Research Ethics Committee (Level 3, Block B. Whitefriars, Lewins Mead, Bristol BS1 2NT, UK; +44 (0)207 104 8071; cornwallandplymouth.rec@hra.nhs.uk), ref: 21/SW/0051

Study design

Observational non-randomized

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Optimising and recording data from patients using temporary pacemakers after cardiac surgery with the aim of building a pacing simulator

Interventions
We will recruit 25 patients at Harefield Hospital who already have temporary pacemakers after cardiac surgery. We will then perform the usual safety checks on enrolled participants within 72 hours of surgery and modify the pacemaker settings to find the settings that achieve the highest blood pressure.
During the setting changes we will record a number of measurements. Blood pressure will be measured via an arterial line (a plastic tube inserted into an artery in the wrist that directly measures the blood pressure) and also via a device that measures blood pressure with a sensor placed on the fingertip. The electrical activity of the heart will be measured by electrodes placed on the surface of the chest, otherwise known as an electrocardiogram (ECG). A set of tubing inserted into one of the large veins in the neck will measure pressure in the veins. Finally, ultrasound images of the heart (an echocardiogram) will also be taken during the setting changes to measure, amongst other things, how quickly blood is travelling in the heart using different settings.
The collection of data from each participant will take 1-2 hours. They will undergo no additional invasive procedures. The collection of data will take less than one year.

Intervention Type
Other

Primary outcome measure
Accuracy of arrhythmia classification by percentage correct compared to diagnosis from clinician from recordings taken during the pacemaker optimisation

Secondary outcome measures
Improvement in confidence of clinicians in adjusting temporary pacemaker after using the simulator compared to before using the simulator, as measured by the Student Satisfaction and Self-Confidence in Learning Scale (SCLS)

Overall study start date

31/10/2020

Completion date
22/03/2023

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Undergoing open cardiac surgery: Coronary Artery Bypass Surgery (CABG), aortic, mitral and tricuspid valve surgery, or combinations of the above, that will require the placing of temporary epicardial wires
3. Any left ventricular function
4. Ability to give valid consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25

Key exclusion criteria
1. Aged under 18 years
2. Inability to give informed consent
3. Permanent pacemaker already in situ

Date of first enrolment
01/07/2021

Date of final enrolment
01/07/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Harefield Hospital
Hill End Road
Uxbridge
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UB9 6JH

Sponsor information

Organisation
Royal Brompton & Harefield NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
https://www.rbht.nhs.uk/research/research-office

ROR
https://ror.org/02218z997

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Brompton and Harefield NHS Foundation Trust

Alternative Name(s)
Royal Brompton & Harefield NHS Foundation Trust

Funding Body Type

Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/02/2024

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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?
Participant information sheet	version 1.2	03/05/2021	19/08/2021	No	Yes
HRA research summary			28/06/2023	No	No
Other publications	A comparison of different methods to maximise signal extraction when using central venous pressure to optimise atrioventricular delay after cardiac surgery	01/04/2024	09/10/2024	Yes	No