ISRCTN14600175 https://doi.org/10.1186/ISRCTN14600175

Observational study – patients undergoing physiological pacing (His Bundle) – analysing the electrical information obtained at the time of implant

Submission date
08/04/2019

Recruitment status
No longer recruiting

Registration date
08/04/2019

Overall study status
Completed

Last Edited
18/10/2021

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Nowadays, pacemakers can work out how well the pacemaker is working, and make appropriate changes to the function automatically, so that it is rare that patients need to attend hospital to check how well the pacemaker is functioning.
In the last 5 to 10 years, we have begun to pace the normal electrical conducting system - which helps the heart function better than the older method. However, the electrical signals received by the pacemaker are very different and we need to try and characterise the signals so that the pacemakers can learn to recognise them on future generations of pacemakers.
We wish to help develop specific ways of programming pacemakers to cope with a new technique called His bundle pacing. Pacing the His bundle allows the pacemaker to use the natural conducting pathway activating the heart in a normal rapid fashion, avoiding some of the downsides of traditional right ventricular pacing such as development of heart failure. Current pacemakers do not have specific ways of understanding and managing His bundle pacing. This study involves taking the normal information obtained during the pacemaker implant, storing it and then analysing it later to develop ways of detecting and managing His bundle pacing.

Who can participate?
Patients who need a pacemaker

What does the study involve?
From the participants viewpoint, the implant is undertaken in the normal way. We wish to collect the data obtained during testing in a clear systematic way once alongside the usual x-ray images for later analysis. The procedure itself is the standard procedure.

What are the possible benefits and risks of participating?
The study does not involve additional risk. The benefit is for the future development of pacemakers. Occasionally additional unexpected abnormalities will be picked up during analysis of data which could benefit the patient.

Where is the study run from?
The Great Western Hospital, Swindon, UK

When is the study starting and how long is it expected to run for?
May 2019 to April 2022

Who is funding the study?
The study is supported by the National Institute for Health Research. The equipment to measure the signals is provided by Medtronic, a large medical device company. The signals will be analysed by scientists based at Aston University (Berthold Stegemann) in collaboration with the Bakken Research team from Medtronic.

Who is the main contact?
Dr Paul Foley, p.foley1@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Paul Foley

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
41324

Study information

Scientific Title
High fidelity recording of His bundle electrograms for development of His specific algorithm

Study objectives
Record the electrical signals during implant and during follow up of pacemakers undergoing His Bundle pacing for
standard clinical indications. The aim is to try and develop techniques to allow the pacemaker to automatically recognise His bundle pacing
signals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/03/2019, (Health Research Authority, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; 0207 104 8104; NRESCommittee.WestMidlands-Edgbaston@nhs.net), ref: 19/WM/0065

Study design
Non-randomised Cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Arrhythmia

Interventions
We would like to approach a cohort of patients who are scheduled to undergo pacemaker implants for clinical indications. We would like to ask them to participate in this study. Once the lead is implanted, during routine testing, we will analyse the recordings as per standard implant. We would like the participants to keep the recordings for later analysis. During follow up, we would like to keep the results of routine pacemaker function tests for analysis.

Intervention Type
Other

Primary outcome measure
His Bundle pacing associated electrocardiograms (EGMS) at implant and follow up.

Secondary outcome measures
To try and determine algorithms to recognise His Bundle pacing and differentiate from other cardiac stimulation during pacemaker stimulations.

Overall study start date
01/02/2019

Completion date
01/04/2022

Eligibility

Key inclusion criteria
1. Patients undergoing His bundle pacing

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Key exclusion criteria
1. Failure to capture the His bundle
2. Unable to consent

Date of first enrolment
01/05/2019

Date of final enrolment
01/04/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Great Western Hospital
Marlborough Road
Swindon

United Kingdom
SN3 6BB

Sponsor information

Organisation
Great Western Hospitals NHS Foundation Trust

Sponsor details
Great Western Hospital
Marlborough Road
Swindon
England
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04g6v3637

Funder(s)

Funder type
Industry

Funder Name
Medtronic

Alternative Name(s)
Medtronic Inc.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

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
Depending on findings this may generate a publication or may just help develop pacemaker algorithms

Intention to publish date
01/06/2022

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication
All usual data will be stored using NHS password protected servers which are physically locked protected by security card access (audit trail) and CCTV. ECGs and fluoroscopic images for analysis will be exported and data anonymity will be preserved. All data will be held on password protected servers. The computers are password protected, and the hospital is accessed by security cards to open doors (audit trail). In addition, there is very high quality and high definition CCTV throughout the hospital.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v3.0	04/04/2019	08/04/2019	No	Yes
HRA research summary			28/06/2023	No	No