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Optimising Pacemaker Therapy (OPT-PACE)

Submission date
17/05/2013

Recruitment status
No longer recruiting

Registration date
17/05/2013

Overall study status
Completed

Last Edited
09/08/2019

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Permanent pacemakers are a common treatment for slow heart beats. In the UK 300,000 people have a pacemaker, and each year another 36,000 receive them. All of these patients are usually seen yearly to have their device checked. However, pacemaker technology is now very reliable, batteries last well over 5 years, and many patients require their pacemaker only occasionally as a backup.
Most visits involve checking the battery and the leads which, in the absence of symptoms, might be unnecessary. Pacemaker patients are at risk of developing other problems including heart failure which puts them at higher risk of hospitalisation and death. For those under follow-up, no mechanism exists to identify whether they might have heart failure, and for those receiving new implants, it is unclear which will go on to develop heart failure. Also, whether optimal heart failure treatment with a multidisciplinary team reduces the chances that they will be hospitalised is also unproven.
The aims of this study are to identify which patients are likely to develop complications and therefore which patients could be seen less frequently; to identify which patients should undergo screening for heart failure; and to find out whether such screening is cost-effective for reducing hospitalisation and death.

Who can participate?
Male and female patients aged 18 or over that have undergone (or had an attempted) implantation of a standard right ventricular permanent pacemaker.

What does the study involve?
During a routine pacemaker visit, patients will be invited to participate and will be randomly selected to either have an ultrasound of their heart (echocardiogram) or usual care. This will explore whether they have any structural heart problems.

What are the possible benefits and risks of participating?
Patients will be randomly allocated to having an ultrasound scan or usual care. The identification of previously unknown heart muscle weakness can lead to additional treatment and additional hospital visits which may or may not be of benefit (hence the study).

Where is the study run from?
The study will be running in Leeds, Bradford and Harrogate hospitals (UK)

When is the study starting and how long is it expected to run for?
June 2013 to March 2018

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01819662

Protocol serial number
14378

Study information

Scientific Title
Stratified care for patients with pacemakers

Acronym
OPT-PACE

Study objectives
Permanent pacemakers are a common treatment for slow heart beats. In the UK 300,000 people have a pacemaker, and each year another 36,000 receive them. All of these patients are usually seen yearly to have their device checked.

However, pacemaker technology is now very reliable, batteries last well over 5 years, and many patients require their pacemaker only occasionally as a backup.

Most visits involve checking the battery and the leads which, in the absence of symptoms might be unnecessary. Pacemaker patients are at risk of developing other problems including heart failure which puts them at higher risk of hospitalisation and death. For those under follow-up, no mechanism exists to identify whether they might have heart failure, and for those receiving new implants, it is unclear which will go on to develop heart failure. Also, whether optimal heart failure treatment with a multidisciplinary team reduces the chances that they will be hospitalised is also unproven.

My proposal therefore has three main aims:
1. Based on pacing indications and patient factors, to identify which patients are likely to develop complications and therefore which patients could be seen less frequently
2. To validate and refine a simple risk score to help identify which patients in pacing clinic should undergo screening for heart failure; and
3. To establish whether such screening and subsequent optimisation of those with heart failure is clinically and cost-effective for reducing hospitalisation and death.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Yorkshire, 25/10/2012, ref: 12/YH/0487

Study design
Interventional and observational randomised; Design type: Diagnosis, Prevention, Screening, Treatment, Cohort study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Heart Failure

Interventions
Interventions: The project has two workpackages and a randomisation and then a cohort phase. During a routine pacemaker visit, patients will be invited to participate and will randomly be selected to have an ultrasound of their heart (echocardiogram) or not. In the presence of left ventricular dysfunction a policy of optimised therapy according to local policy as though this was 'normal' heart failure will be instituted.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Hospitalisation and mortality; Timepoints: 12 months

Key secondary outcome(s))
No secondary outcome measures

Completion date
01/03/2018

Eligibility

Key inclusion criteria
1. Work package 1: We will prospectively enrol consecutive patients that have undergone (or had an attempted) implantation of a standard right ventricular (RV) permanent pacemaker (PPM) at Leeds General Infirmary into this observational study.
2. Work package 2: We will prospectively enrol consecutive attendees at pacemaker clinics in three hospitals in West Yorkshire.
3. Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Work package 1: We will exclude patients with implantable cardioverter defibrillators (ICD) and cardiac resynchronisation pacemakers (CRT), but there will be no other exclusion criteria for adults (>18 years).
2. Work package 2:
2.1. We will exclude patients with implantable cardioverter defibrillators and cardiac resynchronisation pacemakers
2.2. Patients must be >18 years of age
2.3. Have had their pacemaker for >=12 months and
2.4. Not be under heart failure follow-up

Date of first enrolment
01/06/2013

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Light Laboratories
Leeds
United Kingdom
LS2 9DA

Sponsor information

Organisation
University of Leeds (UK)

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
NIHR (UK) - Clinician Scientist Award Scheme; Grant Codes: NIHR-CS-012-032

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article	protocol	17/07/2019	09/08/2019	Yes	No