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Reveal and Carelink (Real Care): Does using remote monitoring in combination with Implantable Loop Recorders reduce the time to diagnosis?

Submission date
05/03/2014

Recruitment status
No longer recruiting

Registration date
28/04/2014

Overall study status
Completed

Last Edited
21/05/2021

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
There are many reasons why people collapse or suffer from palpitations (pounding or racing of the heart). After full investigation the cause of the patient's symptoms may remain unexplained or there may be suspicion but not evidence that it is due to an irregularity in the rhythm of the heart. If the heart is going too slowly or too fast, it could be the reason for the symptom. A patient's doctor may suggest prolonged monitoring of the heart by means of an implantable loop recorder (ILR). ILRs are small diagnostic devices for monitoring and recording the heart's electrical signals/electrocardiographs (ECGs) for extended periods of time. The device can be fixed for up to 36 months in some cases. ILRs are implanted under local anaesthetic just beneath the skin, most often on the left side of the chest. The aim of this study is to compare traditional methods of implantable loop recorder follow-up within the County Durham and Darlington NHS Foundation Trust hospitals with a newly available method that means patients can be followed up from their own home.

Who can participate?
The study is available to all patients who receive a Medtronic ILR and are over 18 years of age with access to a landline telephone.

What does the study involve?
Patients are randomly allocated to one of two groups: experimental group patients receive the remote monitoring equipment and those in the control group receive usual care. The research will identify how well patients accept the remote monitoring system and if it can improve our time to diagnosis.

What are the possible benefits and risks of participating?
The benefits of this study lay in ensuring that future implantable loop recorder patients receive the best possible care and a diagnosis is reached in the safest and most efficient way. There are no perceived additional risks involved with taking part in the study. However, if any potential

risks are highlighted throughout the course of the study, participants would be informed and asked if they would like to continue to take part or leave the study.

Where is the study run from?
The study is run from hospitals within County Durham and Darlington NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
The study will recruit patients between November 2013 and November 2015 and will follow patients up for two years with the last patient leaving the study in November 2017.

Who is funding the study?
County Durham and Darlington NHS Foundation Trust (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Real Care - MED-248-201

Study information

Scientific Title

Reveal and Carelink (Real Care): Does using remote monitoring in combination with Implantable Loop Recorders reduce the time to diagnosis? A randomised controlled trial

Acronym
Real Care

Study objectives
Utilising Carelink remote monitoring for County Durham and Darlington NHS Foundation Trust implantable loop recorder patients can reduce the time taken to reach a diagnosis of whether there is a cardiac cause for their symptoms or not, when compared to traditional in-office follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Durham University's School of Medicine, Pharmacy and Health Sub-Ethics Committee, 28/08/2013, Ref. ESC2/2013/08
2. Health Research Authority NRES Committee North East - Sunderland - Ref. 13/NE/0297

Study design
Single-centre prospective randomised clinician-blinded, using consecutive, fully informed patients. Data analysis to be carried out on an intention-to-treat basis.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Syncope / TLoc and Palpitations - Cardiovascular Medicine

Interventions
Experimental Group - Addition of Carelink remote monitoring equipment provided by Medtronic Inc. Data from implantable loop recorder to be viewed fortnightly.

Patients in the Control Group will follow the standard care pathway.

Patients will spend a maximum of 2 years in the study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Time to patient diagnosis or non-cardiac outcome within the 24-month follow-up period.

Secondary outcome measures
1. Which follow-up method promotes the least device memory saturation
2. Are more patients diagnosed via automated recordings or manual recordings
3. Impact in terms of time and resources required of running remote monitoring clinics within CDDFT hospitals

Patients will be reviewed at baseline (1 month post implant/enrolment) then 6 monthly or if symptoms occur for control group patients and fortnightly or if symptoms occur for experimental group patients.

A participant is considered to have a cardiac diagnosis if they are treated for a cardiac problem that could be the cause of their symptoms, such as asystole, bradycardia or tachycardia other than sinus tachycardia. Treatment could be in the form of medication, a cardiac device (pacemaker, ICD or CRT) or any other form of cardiac rate or rhythm management therapy. Participants may receive a non-cardiac diagnosis as the cause for their symptoms; this is considered to be the case if a participant makes a manual recording whilst symptomatic on two or more occasions. Finally, previous data suggests that there will be a small number of participants that will not have any symptoms during the 24-month follow-up period, these participants will receive no diagnosis.

Overall study start date
20/11/2013

Completion date
20/11/2017

Eligibility

Key inclusion criteria
1. Implanted with a Medtronic Reveal DX or XT ILR
2. Over 18 years of age
3. Are themselves cognitively capable of consenting
4. Have the ability, or have a willing and appropriate adult to use any equipment and comply with the control and Carelink pathway
5. Are able to communicate using, or understand instructions given in, English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Total 80 participants, 40 control patients and 40 experimental patients

Key exclusion criteria
1. Patients that do not have access to a landline telephone
2. If they have documented cognitive impairment that means that they are unable to consent for themselves
3. Do not have the ability or a willing and appropriate adult to comply with the use of any equipment or they are unable to follow the control and Carelink care pathways
4. Patients that cannot communicate using, or understand instructions given in, English

Date of first enrolment
20/11/2013

Date of final enrolment
20/11/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Darlington Memorial Hospital
Darlington
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Sponsor information

Organisation
County Durham and Darlington NHS Foundation Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03vamsh08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
County Durham and Darlington NHS Foundation Trust (UK) - Real Care - MED-248-201 - CDDFT Springboard Grant

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Thesis results			21/05/2021	No	No
HRA research summary			28/06/2023	No	No