

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	☐ Prospectively registered ☐ Protocol
Registration date 28/04/2014	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/05/2021	Condition category Circulatory System	☐ 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?

Mr Gareth Pounds

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

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.

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Study participating centre

Darlington Memorial Hospital

Darlington

United Kingdom

DL3 6HX

Sponsor information

Organisation

County Durham and Darlington NHS Foundation Trust (UK)

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

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