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Remote monitoring in heart failure patients

Submission date
23/06/2016

Recruitment status
No longer recruiting

Registration date
27/06/2016

Overall study status
Completed

Last Edited
05/06/2017

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Chronic heart failure (CHF) is a long-term condition where the heart has become weakened and isn't able to pump blood around the body effectively. It is very common, meaning that related hospital admissions and healthcare costs continue to rise. With the ageing population and improving treatment of coronary artery disease (blockage of the main heart arteries), the incidence of heart failure will continue to increase rapidly. Many patients with heart failure now have implantable devices to help manage their condition. The purpose of this study is to help to understand how to better use the information from these devices, in order to prevent death or admission to hospital, and to improve health-related quality of life. Until recently all patients who have a pacemaker (a device which uses electrical pulses to maintain a normal heart rhythm) or defibrillator (a device which shocks the heart into a normal rhythm) fitted have been required to attend routine clinic appointments in hospital to have their device readings checked. Because of advances in technology, some devices now allow physicians to retrieve that information without the need for patients to attend device clinics. Patients with these devices can now transmit their device data from the comfort of their own home. This is done with a small monitor that is used to send device data over a telephone line to a secure server. Clinical staff then access and review the device data remotely. The aim of this study is to see how best hospital study teams can manage patients care using these advances in technology.

Who can participate?
Adults with heart failure who have had an implantable device for at least six months that is suitable for remote monitoring.

What does the study involve?
Patients with devices are randomly allocated to one of two groups. Those in the first group are monitored using remote management technology for heart failure assessment using specific care guidelines. This involves being invited to have their device checked weekly from home over the internet. Those in the second group follow their local hospital routine standard of care which may involve some remote follow up and/or attending hospital device clinics (generally every three to six months). Participants in both groups are contacted by telephone after three, six and twelve months and then yearly until the end of the study (minimum of two years) to ask about their progress. All participants also complete a number of questionnaires to return by post at these times to assess their quality of life.

What are the possible benefits and risks of participating?
There are no known benefits or risks involved with participating in this study.

Where is the study run from?
Southampton General Hospital (lead centre) and eight other NHS hospitals in England (UK)

When is the study starting and how long is it expected to run for?
September 2011 to January 2016

Who is funding the study?
1. British Heart Foundation (UK)
2. Boston Scientific Ltd (UK)
3. Medtronic Ltd (UK)
4. St Jude Medical Ltd (UK)

Who is the main contact?
1. Mrs Sue Kitt (public)
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2. Professor Martin Cowie (scientific)
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
UKCRN10383

Study information

Scientific Title
REmote Monitoring and evaluation of implantable devices for management of Heart Failure patients

Acronym
REM-HF

Study objectives
The aim of this study is to assess whether patient-independent remote monitoring using implanted device technology and deployed in clinical pathways designed for chronic management of heart failure in the home will significantly reduce all-cause patient mortality and cardiovascular hospitalisation in the context of NHS care and will be more cost effective than usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire and The Humber- Sheffield, 17/05/2011, ref: 11/YH/0062

Study design
Multicentre randomised non-blinded interventional controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Heart failure

Interventions
Participants are randomised to one of two groups.

Group 1: Participants will be set up with remote device monitoring and arrangements made for a weekly device download to be transmitted to their local study hospital. Some participants may already use remote monitoring but this will be on a much less frequent basis, usually 3 to 6 monthly. The weekly downloads will be reviewed by the nurse or cardiac technician who are the "trained study remote monitor". The monitor will review the weekly downloads and take any appropriate actions which are then documented as part of the study data.

Group 2: Participants will have their device care managed according to the usual care in their local hospital.

Both groups will be contacted by telephone at 3, 6, 12 month and yearly following enrolment to ask about their progress. Data regarding their progress will be collected from the telephone follow up and supported by hospital and GP medical records. All participants will be required to complete "Quality of Life" (QOL) questionnaires at baseline, 3, 6, 12 and 24 months following enrolment. The latter 4 QOL questionnaires may be sent in the post. Depending on the date of their enrolment each participant will be followed up in the study for up to 4 years with a minimum of 2 years follow up.

Intervention Type
Device

Primary outcome(s)
Combined all-cause mortality (ACM) or unplanned cardiovascular (CV) hospitalisation (whichever comes first) rate is determined through follow up interviews at 3, 6, 12 month, 2 years and for the early recruiters up to 4 years. Data will be collected from a combination of participant interviews, reviewing hospital and GP records and by obtaining copies of death certificates where available from the Health and Social Care Information Centre.

Key secondary outcome(s))
Unless otherwise stated, secondary outcome measures will be measured at the last follow-up or at the last available observation within the two year follow-up period.

1. Time to death is measured by time from randomisation to date of death
2. Time to a cardiovascular related death is measured by time from randomisation to date of death
3. Time to a non-cardiovascular related death is measured by time from randomisation to date of death
4. Time to first unplanned hospitalisation for cardiovascular reasons or cardiovascular related death is measured by time from randomisation to date of event
5. Time to first unplanned hospitalisation for non-cardiovascular reasons or death by any cause is measured by time from randomisation to date of event
6. Time to first unplanned hospitalisation for cardiovascular reasons is measured by time from randomisation to date of event
7. Time to first unplanned hospitalisation for non-cardiovascular reasons is measured by time from randomisation to date of event
8. Total number of unplanned hospitalisations is measured by the total number of these episodes during the follow up period
9. Total number of unplanned hospitalisations for cardiovascular reasons is measured by the total number of these episodes during the follow-up period
10. Health related quality of life is measured using the SF12 (physical and mental health components) at baseline,3 month, 6 month, 12 month, 1 and 2 years

11.Health related quality of life is measured using the EQ5D at baseline, 3 month, 6 month, 12 month, 1 and 2 years
12.Health related quality of life is measured using the KCCQ at baseline, 3 month, 6 month, 12 month, 1 and 2 years
13. Number and cost of hospitalisations is measured by applying the national tariff costs to the hospitalisation episodes
14. Difference in cost of resources consumed is measured by applying appropriate costs to both arms of the studies and comparing these for the duration of the study
15. Difference in cost of cardiovascular related health care use is measured by applying the appropriate costs to both arms of the studies and comparing these for the duration of the study
16. Incremental costs per quality-adjusted life years (QALYs) is measured by dividing the difference in costs between both arms of the study by the difference in QALYs between the arms

Completion date
31/01/2016

Eligibility

Key inclusion criteria
1.Participants will all have received an Implantable Cardioverter Defibrillator (ICD), Cardiac Resynchronisation Therapy-Pacemaker (CRT-P) or Cardiac Resynchronisation Therapy-Defibrillator (CRT-D) at least six months previously, for the treatment and monitoring of chronic heart failure
2.Be on stable medical therapy for CHF for 6 weeks prior to recruitment
3.Will have the ability to independently comprehend and complete Quality of Life Questionnaires
4. Will have the ability to give informed consent
5. Will be on optimal medical therapy according to the treating physician, working to NICE Guidelines
6. Will have had their device programmed to give optimal therapy according to the treating physician
7. Will have symptomatic heart failure (i.e. NYHA Class II to IV) documented at the time of study enrolment
8. Will be at least 30 days post any device change or lead replacement procedure
9. Will be at least 3 months post any cardiac surgical procedure
10. Will be at least 3 months post acute myocardial infarction

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

1. Unable to use the technology due to mental or physical limitations
2. Less than 18 years old
3. Pregnancy
4. On a heart transplant list
5. Life expectancy of < one year (non cardiovascular related) in the opinion of the treating physician
6. Current device related complications, e.g. wound infection or haematoma, lead fracture
7. Device implanted less than 6 months previously
8. Patients unable to understand written and spoken English.

Date of first enrolment
29/09/2011

Date of final enrolment
31/03/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southampton General Hospital
University Hospital Southampton NHS Foundation Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Royal Brompton Hospital
Royal Brompton and Harefield NHS Foundation Trust
Sydney Street
London
United Kingdom
SW3 6NP

Study participating centre
Blackpool Victoria Hospital
Blackpool Teaching Hospitals NHS Foundation Trust
Whinney Heys Road
Blackpool

United Kingdom
FY3 8NR

Study participating centre
St Thomas' Hospital
Guys and St Thomas' Hospital NHS Foundation Trust
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Leeds General Infirmary
Leeds Teaching Hospital NHS Trust
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre
Glenfield Hospital
University Hospitals of Leicester NHS Trust
Groby Road
Leicester
United Kingdom
LE3 9QP

Study participating centre
Liverpool Heart and Chest Hospital
Liverpool Heart and Chest Hospital NHS Foundation Trust
Thomas Drive
Liverpool
United Kingdom
L14 3PE

Study participating centre
Wythenshawe Hospital
University Hospital of South Manchester NHS Foundation Trust
Southmoor Road
Wythenshawe
Manchester

United Kingdom
M23 9LT

Study participating centre
Freeman Hospital
Newcastle Hospitals NHS Foundation Trust
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Funder Name
Boston Scientific Corporation

Alternative Name(s)
Boston Scientific, Boston Scientific Corp., BSC

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

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
St. Jude Medical

Alternative Name(s)
St. Jude Medical, Inc., SJM

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

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?
Results article	results	07/08/2017		Yes	No
Protocol article	protocol	01/09/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes