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Developing care pathways for remote monitoring

Submission date	Recruitment status	[ ] Prospectively registered
23/04/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/04/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/09/2016	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
More heart failure patients now receive device-based treatment in the form of implantable cardioverter defibrillators (ICDs) and cardiac resynchronisation defibrillators (CRT-D), but despite this, admissions and healthcare costs relating to heart failure continue to rise. Recent device technology that transmits data from an implanted cardiac pacing device to a monitoring station in the home can predict left ventricular heart failure deterioration. The aim of this study was to evaluate the relative costs and the acceptability of conventional and remote care pathways designed to monitor implanted device technology for chronic disease in the home.

Who can participate?
Heart failure patients over 16 years old with implanted ICD/CRT-D devices.

What does the study involve?
The remote monitoring group (consisting of patients with implanted Medtronic devices with the Optivol™ intrathoracic impedance feature) were compared with control patients implanted with devices that did not have access to remote monitoring and who followed the usual standard pathway of care. The remote monitoring group were further randomly allocated into two groups, either remotely downloading daily for three months and then weekly for three months, or downloading weekly for the six-month period. The downloads were reviewed on the day of download by the study nurse, who reported to the consultant responsible and made medication or programming changes where required.

What are the possible benefits and risks of participating?
There are no disadvantages or risks as the care will be the same whether the volunteer chooses to participate or not. It is hoped that the results may help us develop better ways of preventing hospital admissions for heart pump failure and heart rhythm abnormalities in the future.

Where is the study run from?
Southampton General Hospital (UK).

When is the study starting and how long is it expected to run for?
The study ran from February 2009 to August 2009.

Who is funding the study?
Medtronic Ltd (UK).

Who is the main contact?
Ms Lisa Fletcher
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Contact information

Type(s)
Scientific

Contact name
Ms Lisa Fletcher

Contact details
Southampton General Hospital
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SO16 6YD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
6877

Study information

Scientific Title
A pilot study developing care pathways for remote monitoring

Study objectives
The aim of this study is to determine and document a projects viability to allow development of a future larger prospective randomised control trial to determine morbidity, cost efficacy and mortality of remote disease management for heart failure and arrhythmia burden.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Berkshire Research Ethics Committee, 20/10/2008, ref: 08/H0505/131

Study design
Randomised interventional process of care trial with qualitative study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
6 month study of two groups.

Group 1:
Observation so diary entry and Quality of life questionnaires only.

Group 2 (interventional):
Study group download from device using Carelink. Divided into A and B:
Group A: daily downloads for three months and then weekly for remainding three months
Group B: weekly download for the whole duration - six months

Based on the information obtained from the downloads will determine if treatment needed to be changed - i.e., medication or programme changes to device.

Follow up length: 0 months
Study entry: Other

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Quality of Life is measured uisng the Living with Heart failure Minnesota Life Score and 36-item short form health survey (SF-36) at baseline, 1, 3 and 6 months

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/02/2009

Completion date
31/08/2009

Eligibility

Key inclusion criteria
All participants:
1. Be on stable medical therapy for 6 weeks prior to recruitment
2. Have the ability to independently comprehend and complete QOL Questionnaires
3. Have an episode of New York Heart Association (NHYA) class III heart failure
4. Be on optimal medical therapy
5. Male and female, lower age limit of 16 years

Group 2 additional criteria:
6. Must be implanted with a Medtronic Device that has the optivol feature
7. Have had a cardiac device implanted for at least 3 months prior to recruitment
8. Will have had no device related complications

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Key exclusion criteria
1. If unable to use the technology due to mental or physical limitations
2. Less than 16 years old
3. Pregnancy

Date of first enrolment
01/02/2009

Date of final enrolment
31/08/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
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Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

Sponsor details
Southampton General Hospital
Tremona Road
Southampton
England
United Kingdom
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Sponsor type
University/education

Website
http://www.soton.ac.uk/

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Industry

Funder Name
Medtronic Ltd (UK)

Results and Publications

Publication and dissemination plan
There are no plans to publish this study.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available