# Developing care pathways for remote monitoring

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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
lisa.fletcher@suht.swest.nhs.uk

# Contact information

### Type(s)

Scientific

#### Contact name

Ms Lisa Fletcher

#### Contact details

Southampton General Hospital E Level Research Office Tremona Road Southampton United Kingdom 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 SO16 6YD

# Sponsor information

### Organisation

Southampton University Hospitals NHS Trust (UK)

### Sponsor details

Southampton General Hospital Tremona Road Southampton England United Kingdom SO16 6YD

### 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