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Implantable Loop Recorders in Haemodialysis Patients

Submission date
26/06/2017

Recruitment status
No longer recruiting

Registration date
28/06/2017

Overall study status
Completed

Last Edited
14/10/2022

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
Haemodialysis (also known as dialysis) is a therapy option for those whose kidneys do not work. This involves removing water and excess electrolytes (chemicals that maintain muscles) in a three to four hour session attached to the dialysis machine three times a week. It has been suggested that sudden cardiac death (SCD) contributes around 50% of cardiovascular mortality and up to 27% of all causes of death in haemodialysis patients. Identifying deaths that are truly sudden and cardiac can be challenging particularly in kidney failure and the true burden of arrhythmias and arrhythmic deaths in this population has been poorly studied. The aim of this study is to use a implantable loop recorder (ILR) device inserted into dialysis patients to continuously record their ECG (heart rhythm) and monitor cardiac events until death, battery life depletion of the ILR, explant of the device (for whatever reason in order to offer the longest follow up period of continuous ECG monitoring in this population to date.

Who can participate?
Adults aged 18 and older with end stage renal failure who are receiving regular dialysis

What does the study involve?
Participants who receive dialysis three times are week receive the ILR device. It is implanted in the left chest area. This device provides continuous ECG monitoring and data can be reviewed remotely by staff. Participants are trained on how to download their own data at each of their dialysis sessions. Device downloads are reviewed by researchers for any significant cardiac events. Participants are followed up until the end of the battery life, death or they require the ILR to be removed.

What are the possible benefits and risks of participating?
There are no notable benefits with participating, however it does help develop a better understanding of heat rhythm abnormalities for dialysis patients. There are potential risks of infection as well as pain/bruising associated with the implanting of the device.

Where is the study run from?
1. Southampton General Hospital (UK)
2. Queen Alexandra Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2009 to December 2017

Who is funding the study?
Medtronic PLD (UK)

Who is the main contact?
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Contact information

Type(s)
Public

Contact name
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SO16 6YD

Additional identifiers

Protocol serial number
8356

Study information

Scientific Title
Cardio-Renal Arrhythmia Study in Haemodialysis patients using Implantable Loop Recorders (CRASH-ILR)

Study objectives
An implantable loop recorder may identify whether certain patients who have end stage renal disease on dialysis are at an increased risk of cardiac arrhythmias.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central – Hampshire A, 04/12/2009, ref: 09/H0502/121

Study design
; Interventional; Design type: Device

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Cardiovascular disease, Primary sub-specialty: Arrhythmia

Interventions
Participants are recruited from a single tertiary nephrology centre in the UK and all were receiving haemodialysis three times a week.

Participants receive the intervention of the having an implantable loop recorder (ILR) device (Reveal XT®) implanted in the left parasternal region. ILRs are routinely used in clinical practice for the diagnosis of arrhythmias, have around a 3 year battery life and the data they capture can be transmitted using a secure website from a telephone landline or mobile to a computer. ILRs are cardiac devices which provide continuous ECG monitoring & this data can be transmitted regularly for review remotely. Device programming is standardised to include automatic detection of brady/tachy arrhythmias and patient activated recordings. Participants are trained on how to transmit data from their device at each dialysis session via the remote monitoring CareLink system (Medtronic). Every device download (following successful transmission) is manually scrutinised independently by two members of the research team.

Participants are followed up was from their day of implantation to death, explant or end of battery life of ILR depending on whichever came first.

Any cardiac event considered to be of clinical significance was relayed to the nephrologist involved in the patient's care.

Intervention Type
Other

Primary outcome(s)
1. Sudden cardiac death (SCD) is measured using continuous ECG data downloaded from the ILR device. In addition to clinical information and post mortem examination where performed.
2. Implantation of pacing device is measured by reporting the number of pacemakers or defibrillators that were implanted during the course of the study.

Key secondary outcome(s))
Development of significant arrhythmia necessitating medical intervention is measured using continuous ECG data from the ILR device.

Completion date
31/12/2017

Eligibility

Key inclusion criteria

1. End Stage Renal Failure (ESRF)
2. Received regular haemodialysis for a minimum of 90 days prior to study entry and is expected to continue with haemodialysis indefinitely or until renal transplant
3. At least 18 years of age
4. Willing and able to comply with investigational plan and willing to remain available for follow-up through to study closure
5. Willing and able to sign/date the study informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Myocardial infarction in preceding 40 days prior to enrolment
2. Already implanted with a cardiac device, such as pacemaker, defibrillator or implantable loop recorder (ILR)
3. Life expectancy less than one year in the opinion of an Investigator
4. Enrolled in another research study
5. Expected to have poor compliance with the study protocol
6. Pregnancy or breastfeeding
7. Haemodialysis via leftsided tunnelled central venous catheter
8. Expected to require a thoracic magnetic resonance image (MRI)

Date of first enrolment
30/08/2011

Date of final enrolment
23/10/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southampton General Hospital (Lead Site)
CRM Research Office
Mailpoint 46
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Queen Alexandra Hospital
Cardiology Research
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation
Queen Alexandra Hospital

ROR
https://ror.org/04rha3g10

Funder(s)

Funder type
Government

Funder Name
Medtronic Ltd

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/12/2017		Yes	No
Participant information sheet	version V1.47	17/02/2012	28/06/2017	No	Yes
Participant information sheet	version V1.47	17/02/2012	12/07/2017	No	Yes
Protocol file	version 1.5	15/08/2014	14/10/2022	No	No