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Sudden cardiac death in kidney disease

Submission date	Recruitment status	[_] Prospectively registered
15/01/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/03/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
26/03/2020	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic kidney disease (CKD) is a long-term condition where the kidneys don't work as well as they should. Cardiovascular disease is one of the main causes of death in people with kidney disease. Sudden cardiac death (SCD) is the single most common form of death in dialysis patients, accounting for 20% to 30% of all deaths in this cohort. Surprisingly little is known about actual mechanism of SCD in these patients. One reason for clearly insufficient knowledge of arrhythmias has been the lack of adequate means of detecting irregular heartbeats over extended periods of months or years.
Implantable cardiac monitors (ICM) are small devices that used for long-term monitoring of a patient's heart electrical activity.
The aim of this study is to investigate the characteristics of the heartbeat in patients with severe chronic kidney disease.

Who can participate?
Patients with stage 4 or 5 kidney disease aged 18 – 75 years.

What does the study involve?
In this study, we use insertable cardiac monitors (ICM), which is clearly the most advanced method of gathering long-term arrhythmic data. The device is implanted subcutaneously to each patient, which gives us the possibility to monitor the electrical activity of the heart constantly over the follow up of 3 years. The data is collected with remote monitoring.

What are the possible benefits and risks of participating?
The study subjects will not be given any financial remuneration, as they will not have to make extra visits to the hospital because of the study. The participants will receive thorough information about their arrhythmias in the course of the study. They will be monitored closely during the follow up period, and potential life dangering arrhythmias can be detected and a pacemaker implanted when needed.
The subcutaneous implantation of insertable cardiac monitor with local anesthesia is a minor procedure with a minimal risk of complications. Infections and minor bleeding related to implantation of the cardiac monitors are possible, though unlikely, risks for the participants. Other tests performed in the study are noninvasive. The study group has extensive experience with all the tests and devices used in the study, including insertable cardiac monitors.

Where is the study run from?
Päijät-Häme Central Hospital, Finland

When is the study starting and how long is it expected to run for?
November 2011 to December 2020

Who is funding the study?
1. Medtronic Ltd, USA
2. Onni ja Hilja Tuovinen Fund, Finland

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
130789

Study information

Scientific Title
Sudden cardiac death and arrhythmias in end-stage renal disease

Acronym
KSCD

Study objectives
What are the most common arrhythmias in patients with end-stage renal disease in different dialysis modalities, which are the factors affecting the prevalence and incidence of these arrhythmias?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/10/2011, Ethics Committee of the Pirkanmaa Hospital District (The Ethics Committee of Pirkanmaa Hospital District, Post box 2000, 33521, Tampere, Finland; +358 50 329 5667; minna.maa.lahtinen@pshp.fi), ref: R11138 / 2011

Study design
Observational study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
End-stage kidney disease stage IV and V

Interventions
The continuous rhythm monitoring of among the participants of the study was carried out using the Medtronic ICMs (Reveal® DX, Reveal XT™ and Reveal Linq™) (Medtronic Inc, Minneapolis, MN, USA). ICMs will be implanted subcutaneously on the left side of the chest using local anaesthesia. Data retrieval from Reveal XT is performed noninvasively via an induction link when the patients visited the hospital for dialysis or for a routine check-up. The participants have an ambulatory 24-hour ECG recording at the beginning of the study and once a year thereafter. At the beginning of the study, an echocardiogram is performed for each participant.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Medtronic ICMs (Reveal® DX, Reveal XT™ and Reveal Linq™)

Primary outcome(s)
Presence and burden of atrial fibrillation, atrial flutter, bradycardia, sustained and non-sustained ventricular tachycardia, ventricular premature contractions, asystole and ventricular fibrillation are quantified using the data from insertable cardiac monitors over the course of the follow-up time of 3 years

Key secondary outcome(s))
1. Temporal association between dialysis and the arrhythmias using the data from insertable cardiac monitors over the course of the follow-up time of 3 years
2. Prevalence of arrhythmias using the data from insertable cardiac monitors over the course of the follow-up time of 3 years.
3. Survival at 3 years measured using patient records.

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Stage 4 (pre-dialysis, glomerular filtration rate 15-29 mL/min/1.73m²) or stage 5 (end-stage renal disease, <15 mL/min/1.73m² or dialysis)
2. Planned active treatment is either hemodialysis or peritoneal dialysis, or kidney transplantation. The hemodialysis also includes short daily home hemodialysis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Age >75 years
2. Age <18 years
3. Presence of a non-cardiovascular and non-renal disease which limits the expected life-span to less than 1 year
4. Probable noncompliance

Date of first enrolment
09/11/2011

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Finland

Study participating centre
Päijät-Häme Central Hospital
Keskussairaalankatu 7
Lahti
Finland
15850

Study participating centre
Helsinki University Hospital
Haartmaninkatu 4 Rakennus 3
Helsinki
Finland
00290

Study participating centre
Central Hospital of Central Finland
Keskussairaalantie 19
Jyväskylä
Finland
40620

Study participating centre
Satakunta Central Hospital
Sairaalantie 3
Pori
Finland
28500

Study participating centre
Vaasa Central Hospital
Hietalahdenkatu 2-4
Vaasa
Finland
65100

Sponsor information

Organisation
Päijät-Hämeen Keskussairaala

ROR
https://ror.org/02v92t976

Funder(s)

Funder type

Industry

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
Onni ja Hilja Tuovinen Fund

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. Due to the limited number of patients in some participating hospitals, the patients could be identifiable even from the anonymized data sets. According to the concent form signed by the patients, data will be treated confidentially and handled only by the investigators and study nurses.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v1.7	14/06/2019	26/03/2020	No	No