# Sudden cardiac death in kidney disease

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
15/01/2020		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
26/03/2020	Completed  Condition category	Results		
Last Edited		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?
Dr Joonas Rautavaara
joonas.rautavaara@gmail.com

# **Contact information**

### Type(s)

Public

#### Contact name

Dr Joonas Rautavaara

#### Contact details

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# Additional identifiers

# **EudraCT/CTIS** number

Nil known

**IRAS** number

# ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

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

### Secondary study design

Cross sectional study

#### Study setting(s)

Hospital

# Study type(s)

Screening

### Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

# 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 Ling™)

#### Primary outcome measure

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

#### Secondary outcome measures

- 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.

#### Overall study start date

13/09/2011

#### Completion date

31/12/2020

# Eligibility

#### Key inclusion criteria

- 1. Stage 4 (pre-dialysis, glomerular filtration rate 15-29 mL/min/1.73 $m^2$ ) or stage 5 (end-stage renal disease, <15 mL/min/1.73 $m^2$  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

## Age group

Adult

#### Sex

Both

### Target number of participants

80

#### 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

# 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

# Sponsor information

## Organisation

Päijät-Hämeen Keskussairaala

## Sponsor details

Keskussairaalankatu 7 Lahti Finland 15850 +35 00381911 tuomo.nieminen@phhyky.fi

#### Sponsor type

Hospital/treatment centre

#### Website

https://www.phhyky.fi/fi/etusivu/

#### **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

#### **Funder Name**

Onni ja Hilja Tuovinen Fund

# **Results and Publications**

#### Publication and dissemination plan

During year 2020 we intend to publish the prevalence of atrial fibrillation and bradyarrhythmias and the factors associated with if. Later this year, we also intend to compare the effect of different dialysis modalities and kidney transplantation on the incidence of new arrhythmias.

#### Intention to publish date

30/06/2020

#### 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