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A prospective randomised controlled trial to evaluate the prevention of sudden cardiac death using Implantable Cardioverter Defibrillators in dialysis patients

Submission date
02/05/2007

Recruitment status
No longer recruiting

Registration date
02/05/2007

Overall study status
Completed

Last Edited
30/08/2022

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
End-stage renal disease is the last stage of chronic kidney disease, when the kidneys are no longer able to work at a level needed for day-to-day life, and dialysis or a kidney transplant is needed to survive. Despite the dialysis treatment and medications, significant changes occur in blood pressure, fluid balance, calcium, phosphate and potassium levels compared to people with normal functioning kidneys. This is one of the reasons that many cardiovascular (heart) diseases occur in patients on dialysis. This might lead to a heart attack or stroke. Studies in recent years show that the risk of arrhythmias (irregular heart rhythm) is increased notably in patients on dialysis. These arrhythmias may cause the heart to stop pumping (cardiac arrest) and result in death. In some groups of cardiac patients with an increased risk of arrhythmia an implantable cardiac defibrillator (ICD) is implanted. An ICD is a small box that is placed through a small cut below the collarbone under the skin and which is connected to wires running to the heart through the bloodstream. In these patients the ICD identifies and treats serious arrhythmias. Previous research has shown that in dialysis patients who survived cardiac arrest through proper CPR, an ICD can prevent a second cardiac arrest. The aim of this study is to test the effectiveness and possible drawbacks of an ICD to prevent a first cardiac arrest in dialysis patients.

Who can participate?
Patients aged 55 to 80 with end-stage renal disease undergoing dialysis

What does the study involve?
At the beginning of the study all participants undergo an ultrasound examination of the heart and aorta, blood tests, a venogram (x-ray of the veins), and also a CT scan of the heart. These examinations determine whether the participants have severe narrowing in the coronary (heart) arteries or malfunctioning heart valves. The venogram is performed to assess the accessibility of the vessels for ICD implantation. If there turns out to be any abnormalities, the participants are treated by a cardiologist in their own hospital. After these examinations participants are informed whether they have been randomly allocated to receive the ICD or not. Participants

allocated to receive the ICD are admitted for a night to the cardiology department of the Leiden University Medical Centre (LUMC). Implanting the ICD takes about an hour and is done under local anaesthetic. If all goes well participants are discharged the next morning. Blood tests are performed to examine kidney function, electrolytes (salts and minerals found in the blood), genetic factors, and factors that affect the inner lining of blood vessels, which may have a relationship with cardiac arrhythmia. Participants are also asked to fill in a questionnaire about their health.

What are the possible benefits and risks of participating?
The advantage of participation in this study is that cardiovascular (heart) concerns will be checked. Any changes can be detected at an early stage and treated if necessary. There are some risks in the short and longer term associated with the implantation of an ICD. During the operation, there is a small chance that when the vein below the collarbone is accessed the top of the lung is punctured - this usually heals on its own. In addition, haemorrhage (bleeding) may occur after the surgery; in most cases no further treatment is necessary. In the long term, there may be an increased chance of narrowing of the draining vein of the shunt (a special blood vessel created in the arm for dialysis). This can have a detrimental effect on the functioning of the shunt. That is the reason the ICD will be placed on the other side of the shunt arm. There is a risk of inflammation of the ICD system. This risk is about 3% in non-dialysis patients, and in a small recent study, in 2 out of the 31 dialysis patients (6.5%) an infection of the ICD occurred and the ICD system had to be removed again. Further, it is possible that the ICD may deliver an inappropriate shock. With the type of ICD which is used in this study this probability is about 5-6%. This can happen when a non-life-threatening arrhythmia in the atria of the heart occurs and is misinterpreted by the ICD. Usually, this can be prevented by re-programming the ICD.

Where is the study run from?
Leiden University Medical Centre (Netherlands)

When is the study starting and how long is it expected to run for?
April 2007 to May 2019

Who is funding the study?
Biotronik (Germany)

Who is the main contact?
1. Dr RJ Timal
r.j.timal@lumc.nl
2. Prof. Dr. J. Wouter Jukema
j.w.jukema@lumc.nl

Contact information

Type(s)
Scientific

Contact name
Dr R. J. Timal

Contact details
Leiden University Medical Centre
Department of Cardiology, C5-P

PO Box 9600
Leiden
Netherlands
2300 RC
+31 (0)71 526 2020
r.j.timal@lumc.nl

Type(s)
Scientific

Contact name
Prof J. Wouter Jukema

Contact details
Dept of Cardiology - B4-027
Leiden University Medical Center
PO Box 9600
Leiden
Netherlands
2300 RC
+31 (0)71 5266695
j.w.jukema@lumc.nl

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A prospective randomised controlled trial to evaluate the prevention of sudden cardiac death using Implantable Cardioverter Defibrillators in dialysis patients

Acronym
ICD2

Study objectives
In patients on dialysis therapy, aged 55 to 80 years, Implantable Cardiac Device (ICD) therapy will reduce sudden cardiac (arrhythmic) death.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee (MEC) of the Leiden University Medical Centre (LUMC), 17/04/2007, ref: P07.016

Study design
Multicentre randomised active-controlled parallel-group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Implantable cardiac device (ICD), sudden cardiac death (SCD)

Interventions
After the patient has signed the informed consent he will be invited to the Leiden University Medical Centre (LUMC) for the assessment of a Multislice Computed Tomography (MSCT), Transthoracic Echocardiography (TTE), pulse wave velocity of the aorta, X-aorta, laboratory tests and quality of life score list. A MSCT is performed to measure the coronary artery calcification and to exclude significant coronary stenosis. If there will be a more than 70% stenosis in the proximal Left Anterior Descending (LAD) and/or left main coronary artery, irrespective of angina complaints, the patient will be referred to the local cardiologist for further evaluation and treatment. If associated pathology is found on the MSCT or TTE, the patient will be referred to a specialist in their own hospital.

After these assessments randomisation will take place. Patients randomised for ICD therapy will be admitted to the LUMC for one night. In haemodialysis patients, the ICD will be implanted at the contra-lateral side of the arteriovenous fistula. ICD patients will visit the ICD outpatients clinic at the LUMC every six months.

Intervention Type
Mixed

Primary outcome(s)
Sudden cardiac (arrhythmic) death rates. Cause of death will be classified as being caused by arrhythmia, other cardiac, vascular noncardiac, or nonvascular.

Key secondary outcome(s))
1. All cause mortality
2. Incidence and types of ventricular and supra ventricular arrhythmias
3. Relation with Left Ventricular Hypertrophy (LVH), Coronary Artery Calcium (CAC) and arterial stiffness and cardiovascular and sudden cardiac death
4. Safety, costs and quality of life

Completion date
01/05/2019

Eligibility

Key inclusion criteria
1. Patients 55 to 80 years of age
2. End Stage Renal Disease (ESRD)
3. Greater than 90 days after start dialysis

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
188

Key exclusion criteria
1. Possible living kidney donation
2. Terminal congestive heart failure according New York Heart Association (NYHA) class four at time of randomisation
3. Non-arrhythmic medical condition making one-year survival unlikely
4. Excessive perioperative risk for ICD implantation
5. Human Immunodeficiency Virus (HIV) infection
6. Patients with central venous line
7. Acute Myocardial Infarction (AMI) in the last 40 days
8. ICD indication according current guidelines
9. Expected poor compliance with protocol

Date of first enrolment
09/07/2007

Date of final enrolment
13/02/2018

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Centre
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (The Netherlands)

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Industry

Funder Name
Biotronik

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan
The data will be held in the LUMC dept of cardiology. Reasonable requests for collaboration /data sharing will in principle be honoured.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/06/2019	04/11/2019	Yes	No
Results article	qualitative results	01/02/2021	22/02/2021	Yes	No
Results article	Prevalence of central venous stenosis	01/04/2022	30/08/2022	Yes	No
Protocol article	protocol	01/08/2008		Yes	No

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes