A prospective Randomized Controlled Trial to Evaluate the Prevention of sudden cardiac death using implantable cardioverter defibrillators in dialysis patients.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24816

Source
Nationaal Trial Register

Brief title
ICD2 - trial

Health condition

Sudden caridac Death (SCD), implantable cardiac device (ICD), Dialysis patients, risk factors for sudden cardiac death

Sponsors and support

Primary sponsor: Leids University Medical Center (LUMC)
Source(s) of monetary or material Support: Biotronik

Intervention

Outcome measures

Primary outcome

To determine whether ICD therapy in dialysis patients aged 55-80 years results in significant reduction in sudden cardiac (arrhythmic) death rates when compared to no ICD therapy. Cause of death will be classified as being caused by arrhythmia, other cardiac, vascular noncardiac, or nonvascular.

Secondary outcome

1. To determine that prophylactic ICD therapy will result in reduction of all cause mortality in dialysis patients;
2. To assess the incidence and types of ventricular and supra ventricular arrhythmias;
3. To assess the relation with LVH, CAC and arterial stiffness and cardiovascular and sudden cardiac death;
4. To assess the safety, costs and quality of life, of ICD therapy in dialysis patients.

Study description

Background summary

Rationale:
Sudden cardiac death (SCD) is the single largest cause of death in dialysis patients. Implantable Cardioverter Defibrillator (ICD) has demonstrated to reduce the risk of SCD and all cause mortality in high risk patients. Whether ICD therapy benefits dialysis patients is unknown. We therefore designed a prospective randomized study to evaluate the primary prevention of SCD in dialysis patients.
Objective:
The main objective of this study is to assess whether ICD therapy in dialysis patients aged 55-80 years can reduce sudden cardiac (arrhythmic) death. Furthermore we will try to gain more insight in mechanisms of SCD in dialysis patients and try to find risk factors that predict SCD.
Study design:
A prospective randomized open-label trial.
Study population:
Dialysis patients aged 55-80 years.
Intervention (if applicable):
200 patients are randomised in ICD therapy (ICD group), and no ICD therapy (control group)
Main study parameters/endpoints:
It will test the hypothesis that ICD therapy will result in reduction of sudden cardiac (arrhythmic) death in dialysis patients.
Main study parameter is the difference in sudden cardiac (arrhythmic) death between ICD therapy and no ICD therapy groups. Secondly the incidence and types of arrhythmias and

incidence of device-related complications will be evaluated. Furthermore we want evaluate if there is an association between potential risk factors (such as coronary artery calcification, left ventricular hypertrophy en dysfunction; arterial stiffness and endothelial function) and cardiovascular events and sudden cardiac death. Finally QOL and economic assessment will be carried out.

Study objective

In patients on dialysis therapy, aged 55-80 year, inplanatable cardiac device (ICD) therapy will reduce sudden cardiac (arrythmic) death.

Intervention

After patient has signed informed consent he will be invited to the LUMC for the assessment of an MSCT, TTE, pulse wave velocity of the 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 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 1 night. In hemodialysis 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.

Contacts

Public
Leiden University Medical Center
Department of Cardiology C5-P
L.C.R. Hensen
POB 9600
Leiden 2300 RC
The Netherlands
+31 (0)71 5262020
Scientific
Leiden University Medical Center
Department of Cardiology C5-P
L.C.R. Hensen
POB 9600
Leiden 2300 RC
The Netherlands
+31 (0)71 5262020

Eligibility criteria

Inclusion criteria

1. Patients 55 to 80 years of age;
2. End Stage Renal Disease (ESRD);
3. > 90 days after start dialysis.

Exclusion criteria

1. Possible living kidney donation;
2. Terminal congestive heart failure according NYHA class 4 at time of randomization;
3. Non arrhythmic medical condition making 1-year survival unlikely;
4. Excessive perioperative risk for ICD implantation;
5. HIV infection;
6. Patients with central venous line;
7. Acute Myocardial Infarction (AMI) last 40 days;
8. ICD indication according current guidelines;
9. Expected poor compliance with protocol.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2007
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-04-2007
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL924
NTR-old	NTR948
Other	:
ISRCTN	ISRCTN20479861

Study results