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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON44083

Source
ToetsingOnline

Brief title
Implantable cardioverter device in dialysis patients. ICD2 study

Condition

- Cardiac arrhythmias
- Nephropathies

Synonym
sudden cardiac death; arrhythmogenic death

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Biotronik,biotronik. Het gaat om een unrestricted research grand.

Intervention

Keyword: -Dialysis patients, -Implantable cardioverter defibrillators, -risk factors for sudden cardaic death, -Sudden Cardiac Death

Outcome measures

Primary outcome

The primary end point is sudden (arrhythmogenic) cardiac death.

Cause of death will be classified as being caused by arrhythmia, other cardiac,

vascular noncardiac, or nonvascular.

Secondary outcome

Overall Mortality will be a secondary end point.

Other secondary end points are:

Device ralated complications

Measurement of quality of life (QOL).

Economic assessment will be carried out.

Study description

Background summary

Their will be a strong increase in incidence of end stage renal desease the comming years. The risk of death is very high in dialysis patients. With 60% of the total cardiovascular death sudden cardiac death is the largest cause of mortality in dialysis patients. Implantable Cardioverter Defibrillators (ICD) have proven to be effective in prevention of SCD in high risk patients. However many studies have excluded patients with terminal renal insufficiency. Whether benefit occurs in dialysis patients is unknown. We therefore designed a

prospective randomized study to evaluate the primary prevention of SCD in dialysis patients. Futhermore we want to explore some risk factors of sudden cardiac death in this group of patients.

Study objective

The main objective of this study is to assess whether ICD therapy in dialysis patients reduces sudden (arrhythmogenic) cardiac death.
The first secondary end point is to compare total mortality death between the two groups. An other is to evaluate several factors contributing to the arrhythmias in dialysis patients. Furthermore we want to measure the quality of life (QOL) and also an economic assessment will be carried out.

Study design

The ICD2 study is a prospective, randomized controlled study. A total of 200 patients will be randomly assigned in a 1:1 ratio either to receive an ICD (ICD group) of not to receive an ICD (control group).

Study burden and risks

After obtaining informed consent the patient will be invited to perform a TTE, PWV and MSCT of the heart. Futhermore laboratory tests a lateral X-ray of the lumbar abdominal aorta to assess calcification and a quality of life score will be obtained. On patients who received a central venous line in the past a venogram will be performed to assess stenosis of the vena subclavia. Patients will be randomised

Patients randomised for ICD therapy will be admitted for 1 night to the hospital for ICD implantation.
ICD patients will be invited to the ICD outpatient clinic after 2 months and every 6 months thereafter. This visit will be combined at 12 months with laboratory tests, a lateral X-ray of the lumbar abdominal aorta to assess calcification and a quality of life score. A doppler echogram and a venogram of the subclavian vein will be performed in all patients to assess possible central venous stenosis.

The sudden cardiac death incidence in this growing group of patients is in our opinion, a justification of this research. Especially since there are no other large studies available on ICD use in dialysis patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Patients 55 to 80 years of age
-End Stage Renal Disease (ESRD)
-> 90 days after start dialysis
-Not eligible for kidney transplantation or kidney transplantation not expected within 3 years after inclusion;zie protocol p 21

Exclusion criteria

-Terminal congestive heart failure according NYHA class 4 at time of randomization
-Non arrhythmic medical condition making 1-year survival unlikely
-Excessive perioperative risk for ICD implantation
-HIV infection
-Patients with central venous line
-Acute Myocardial Infarction (AMI) last 40 days
-ICD indication according current guidelines

-SCD survivors
-(non) ischemic cardiomyopathy with LVEF<30%Not able to sign informed consent
-Expected poor compliance with protocol
-Inclusion in other study protocols

Study design

Design

Study phase:	4
Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-07-2007
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	Implantable cardioverter device
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	15-03-2007
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	21-08-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	08-11-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	23-03-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	01-03-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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
ISRCTN	ISRCTN20479861
CCMO	NL15033.058.07