EQUAL study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nephropathies
Study type	Observational invasive

Summary

ID

NL-OMON55640

Source
ToetsingOnline

Brief title
EQUAL

Condition

- Nephropathies

Synonym
Kidney failure

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ERA-EDTA (de Europese vereniging voor nefrologie) en Nierstichting.

Intervention

Keyword: Dialysis, Timing, Uremic symptoms

Outcome measures

Primary outcome

1. We will give a description of the progression of uremic signs and symptoms in patients.

2. The effects on survival and quality of life of dialysis start with a high renal function versus low renal function, dialysis start with a high number of symptoms and signs versus low number of symptoms and signs, and starting dialysis versus not starting dialysis will be investigated.

3.We will build models with values of kidney function derived from different methods that assess kidney function, i.e. serum creatinine-based measures like eGFR, 24-hrs urine collection-based measures, and tracer-based measures to develop a tool to assist clinicians in the decision when to start dialysis.

4.We will give a description whether patients were given information about the timing to start dialysis, whether patients were given information in which situations dialysis will be started, whether patients were given sufficient information about hemodialysis and peritoneal dialysis, whether patients had a preference to postpone dialysis or a preference for hemodialysis or peritoneal dialysis, and whether patients felt if they had influence on the decision making regarding the timing of initiation of dialysis. Furthermore, we will describe the reasons for the treating nephrologists why they started or not started dialysis yet in each patient.

5.We will give descriptions of renal Treatment Satisfaction Questionnaire scores for different subgroups.

Secondary outcome

NA

Study description

Background summary

In elderly patients >=65 years with end-stage renal disease (ESRD) dialysis is usually started at an estimated glomerular filtration rate (eGFR) (measure for renal function) of 5 to 15 ml/min/1.73m2. Over the past decade, there has been a trend to start dialysis at higher levels of eGFR to make a so-called *healthy start*.

From the perspective of patient survival and quality of life, the best timing of starting dialysis is unknown. Furthermore, the effect of dialysis start with a high renal function versus low renal function and dialysis start with high number of symptoms and signs and low number of symptoms and signs on survival and quality of life in elderly ESRD patients is unknown. There is increasing evidence that in some countries a substantial number of elderly patients wish to postpone dialysis (or prefer not to start dialysis). Dialysis might indeed be safely postponed or even not started in elderly ESRD patients with adequate prescription of relevant medication and diet. For some patient groups the burden of dialysis may be bigger than the benefit. Moreover, there is considerable doubt whether especially eGFR, but also other serum creatinine-based measures of renal function, can be used in the decision to start dialysis because of their inaccuracy and imprecision to reflect residual renal function in this stage of the disease. There is, however, no agreement on a valid method to measure renal function in advanced chronic kidney disease (CKD) to decide when to start dialysis. Furthermore, it is not known how signs and symptoms of kidney disease (uremic signs and symptoms) develop during the progression of CKD towards the start of dialysis and how these uremic signs and symptoms could be used in decision making for the timing of starting dialysis. In addition, insight in the decision making process regarding ESRD care, involving both nephrologists and patients, is lacking.

Study objective

The aim of our study is to compare outcomes between start of dialysis with higher renal function versus lower renal function and start of dialysis with a few signs and symptoms versus many signs and symptoms, to determine a valid method to measure renal function in advanced CKD in the perspective of starting dialysis, to provide insight in the development of uremic symptoms in elderly ESRD patients, to develop a uremic algorithm (decision tree, score) to be used

for decision making on when to start dialysis, and to provide insight in the decision making process regarding ESRD care. To that end, a prospective cohort study will be performed in elderly patients with CKD (eGFR <= 20 ml/min/1.73m2) progressing towards ESRD in four European countries. In total, 3000 patients (500 from the Netherlands) will be included and followed until death or for maximum four years.

Study design

Prospective, observational, multi-center, international follow-up study with a maximum follow-up of 4 years.

Study burden and risks

The patients will be followed for a period of 4 years in the normal treatment of their kidney disease. For study purposes, on every normal follow-up visit, there will blood drawn, also the patient's nutritional status will be assessed with the help of the SGA(subjective global assessment). De study visits will be planned alongside normal follow-up visits as much as possible, so that the patients don't need to come to the hospital separately for study purposes. After every visit patients will be asked to fill in a questionnaire at home and send this back to the researchers via mail. Patients will be followed for 4 years which means that a patient can have a maximum of 13 study visits. Furthermore, a tracer study with iohexol(omnipaque) will be performed in a small portion of the patients. This is done in order to measure a very accurate kidney function. The iohexol can theoretically cause an allergic reaction, but since the dosage that will be used in this study is extremely low the risks for an allergic reaction are negligible. Furthermore, there is 15 years experience in Sweden with the clinical usage of iohexol to determine a very precise kidney function and there are no reporterd adverse events(http://www.ifcc.org/ifccfiles/docs/130201005.pdf).
The total time burden for patients varies from 1 to 15 hours over the course of 4 years.

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

Incident patients >=65 years with an estimated glomerular filtration of <= 20 ml/min/1.73m2 (based on MDRD) who have no history of transplantation or dialysis.

Exclusion criteria

Patients not able to give informed consent by themselves.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-07-2013
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	10-12-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-02-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-02-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-02-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-10-2013

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-02-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-03-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-03-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-03-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-07-2014

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-09-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-12-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-09-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL38874.018.12