

First steps towards the development of a decision aid for the choice between dialysis and kidney transplantation in older adults - a prospective cohort study

Published: 28-07-2021

Last updated: 17-01-2025

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Ethical review	Approved WMO
Status	Completed
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational non invasive

Summary

ID

NL-OMON54175

Source

ToetsingOnline

Brief title

OldeR-RT study

Condition

- Renal disorders (excl nephropathies)

Synonym

end-stage kidney disease; kidney failure

Research involving

Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis

Source(s) of monetary or material Support: Junior Researcher Call van Jeroen Bosch Ziekenhuis en Radboudumc

Intervention

Keyword: Dialysis, Kidney transplantation, Older adults

Outcome measures

Primary outcome

The main study parameters are (1) the treatment goals and expectations regarding dialysis and KT at baseline, and reflection on these six months and 1.5 year after start of RRT, and (2) prediction model for multiple outcome variables.

Secondary outcome

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Study description

Background summary

A large proportion of patients with end-stage kidney disease (ESKD) are older adults. Older adults with ESKD opting for RRT can choose between dialysis and kidney transplantation (KT), which frequently is a difficult. A decision aid could support patients and their health care professionals facing this dilemma. Unfortunately, such a decision aid is not available yet.

Study objective

The primary objective is to collect data that can be used to develop a *patient-goal driven* decision aid for patients ≥ 65 years old regarding the choice between dialysis and KT, using two different approaches (semi-structured interviews and prediction model development). The secondary objectives of this study are to determine (1) the change in cognitive status, functional status, frailty, and quality of life between baseline and 1.5 year after start of RRT, (2) the incidence of mortality, graft failure, severe infections, surgical complications, hospitalizations in the first 1.5 year after start of RRT, and (3) treatment satisfaction and decisional regret six months and 1.5 year after

start of RRT.

Study design

Multicentre prospective cohort study.

Study burden and risks

Participating in this study is without risks. Participants will have three study visits of about 1* hours. Patients waitlisted for deceased KT can have more study visits, because the baseline measurements will be repeated every six months until KT. The study procedures do not include any invasive procedures, clinical tests, laboratory tests, or psychological or psychiatric investigations.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Elderly (65 years and older)

Inclusion criteria

- Age \geq 65 years old
- Stage 5 CKD: eGFR <15 ml/min/1.73 m² or treated with RRT
- RRT modality: Waitlisted for first deceased donor KT, or first living donor KT with surgery scheduled within six weeks, or dialysis as first RRT modality with start expected within six weeks or maximum of six weeks ago
- Medically fit for both dialysis (HD and/or PD) and KT according to the patients* nephrologist

Exclusion criteria

- Not able to provide informed consent
- Patients with urgent, unplanned dialysis start that were not previously counselled about RRT by a nephrologist

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Completed

Start date (anticipated): 17-11-2021

Enrollment: 96

Type: Actual

Ethics review

Approved WMO

Date: 28-07-2021

Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	15-11-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	24-01-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	22-12-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	25-04-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	18-04-2024
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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

CCMO

ID

NL77777.028.21