

# Nephro-geriatric care pathway

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON20312

### Source

Nationaal Trial Register

### Brief title

POLDER

### Health condition

Nephrology; Kidney failure, chronic; Geriatrics; Frailty; Dialysis

Nierziekten; Nierfalen; Geriatrie; Kwetsbaarheid; Dialyse

## Sponsors and support

**Primary sponsor:** LUMC (in collaboration with: AMC, HagaZiekenhuis, HMC+, Maasstadziekenhuis, MUMC+, Radboudumc, RDGG, St. Antonius ziekenhuis, UMCG, UMCU, VUmc)

**Source(s) of monetary or material Support:** Nierstichting Nederland (Dutch Kidney Foundation)

## Intervention

## Outcome measures

### Primary outcome

The evaluation of the success of implementation in routine care, defined as: A) a minimum of 20 patients per hospital successfully included in the national data registry. B) a minimum of

10 centers included in the present project

## **Secondary outcome**

Determinants of successful implementation of the nephro-geriatric care pathway, including assessment of data, biomaterial completeness and integrity, patient experience, barriers and facilitators identified by professionals.

Our tertiary outcomes are the exploration of the association of geriatric measures with treatment choices, survival, hospital admissions, clinical outcomes and selected biomarkers after 1 year of follow up.

## **Study description**

### **Background summary**

Rationale:

The prevalence of End Stage Renal Disease (ESRD) increases with age, and is associated with poor outcome, especially in older age. Although the benefits of dialysis and/or kidney transplantation have been firmly established for most patient groups, there is a subgroup of patients in whom serious adverse outcomes occur, such as early mortality or accelerated functional and/or cognitive decline. Such adverse events occur more frequently in the older patient with ESRD, as increasing age by definition leads to increased vulnerability and increased susceptibility for side effects of treatment. Furthermore, preserving quality of life (QOL) and the desire to stay independent as much as possible may outweigh longer survival in at least some patients in this age group. However, the risk of poor outcome differs greatly between older ESRD patients due to substantial heterogeneity with respect to the presence of comorbidities and geriatric conditions, such as functional and cognitive impairment and frailty. Despite the growing number of frail and older patients with ESRD, there is a paucity of well-designed, prospective studies in this population which limits the evidence for personalized approaches supporting treatment decisions. A basic set of validated markers for comorbidity, cognitive function and functional status, assessed before starting renal replacement therapy and with a regular follow up, will identify vulnerable patients in a multidimensional approach. Establishing which of these geriatric conditions independently associate with poor outcome and loss of QOL, may ultimately help to better identify those patients at risk for negative outcomes and thus guide informed treatment decisions or preventive interventions.

The recent publications of the guidelines 'Nierfunctievervangende Therapie' and 'Palliatieve Zorg bij Nierfalen' emphasize the importance of a multidimensional approach to the frail patient with ESRD, by recommending the implementation of geriatric assessment of older patients with ESRD when reaching end stage renal disease. Based on the literature, experience from previous studies and focus group interviews with patients and caregivers we designed a nephro-geriatric assessment.

#### Objective:

The overall aim of this project is to prepare implementation of a national registry for chronic care in older patients with ESRD, to study determinants of adverse outcomes, implement interventions and improve outcomes for these patients.

#### Study design:

Implementation study and observational, prospective cohort study.

#### Study population:

Patients with CKD stage 4-5 (eGFR < 20 ml/min), aged  $\geq 70$  years

#### Main study objective:

To study the feasibility of implementing a national pathway for older patients with ESRD in routine care; which includes a geriatric assessment at two timepoints, to capture this data in a national database and collect biomaterial for future research.

### Study objective

Ultimately, the implementation of a geriatric assessment and a national registry in pre-dialysis care for older patients with ESRD will provide insights in determinants of adverse outcomes, inform and benefit decision making trajectories for treatment modality, and will improve outcomes for these patients.

In the present study we hypothesize that implementation of a standardized geriatric assessment and collection of geriatric and clinical data in a national registry is feasible.

### Study design

T0: inclusion, T1: year 1

### Intervention

Systematic assessment of cognitive function, mood, functional status, nutritional status, comorbidity, quality of life, patient preferences, PROMS and biomaterial.

## Contacts

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## Eligibility criteria

### Inclusion criteria

Dutch speaking

>70 years of age

eGFR < 20 ml/min/1.73 m<sup>2</sup> (based on CKD-EPI)

### Exclusion criteria

Illiterate

Unable to give informed consent

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	30-10-2018

Enrollment: 200  
Type: Anticipated

## IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion  
Date: 06-06-2018  
Application type: First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 50178  
Bron: ToetsingOnline  
Titel:

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

No registrations found.

## In other registers

Register	ID
NTR-new	NL7104
NTR-old	NTR7310
CCMO	NL65322.098.18
OMON	NL-OMON50178

## Study results