

Pathway for OLDer patients with Endstage Renal disease (POLDER)

Published: 28-06-2018

Last updated: 19-03-2025

Within the present project we aim for a structural evaluation and registration of multidimensional clinical and geriatric data in all older patients with CKD stage IV and V, who will progress to ESRD, as proposed in the above mentioned guidelines....

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

Summary

ID

NL-OMON50178

Source

ToetsingOnline

Brief title

Nephro-geriatric care pathway (POLDER)

Condition

- Renal disorders (excl nephropathies)
- Age related factors

Synonym

geriatric domains, kidney failure

Research involving

Human

Sponsors and support

Primary sponsor: LUMC

Source(s) of monetary or material Support: Nierstichting

Intervention

Keyword: chronic, Dialysis, Frailty, Geriatrics, Kidney failure

Outcome measures

Primary outcome

Implementation of a care pathway for older patients with ESRD, including a registry for future research to predict and improve outcomes for older patients with ESRD. Primary endpoints are A) the number of patients successfully included in the national data registry and B) the number of centers included in the national consortium.

Secondary outcome

We aim to study the association of geriatric measures with treatment choices, survival, hospital admissions and selected biomarkers after 1 year of follow up, and aim to establish recommendations for further national implementation. Besides, we investigate if the COVID-19 pandemic leads to decreased quality of life, increased feelings of fear and depressive symptoms in patients nearing end stage renal disease.

Study description

Background summary

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, nutritional 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.

Study objective

Within the present project we aim for a structural evaluation and registration of multidimensional clinical and geriatric data in all older patients with CKD stage IV and V, who will progress to ESRD, as proposed in the above mentioned guidelines. We will implement a care pathway including a systematic nephro-geriatric assessment and set up a national multi-center registration of geriatric patients who will reach ESRD in the Netherlands to investigate the association of geriatric measures and biomarkers with negative outcomes.

Study design

Implementation study and observational, prospective cohort study.

Study burden and risks

Study specific burden consists of a taking blood sample at baseline and systematic collection of outcome measures consisting both of routinely collected clinical parameters and repeated collection of Patient reported outcomes (PROM*s). The standardized nephrogeriatric assessment at baseline and repeated geriatric assessments during follow-up are part of routine clinical care as outlined in the recent guidelines **Nierfunctievervangende Therapie** and

Palliatieve Zorg bij Nierfalen.

Contacts

Public

LUMC

Albinusdreef 2
Leiden 2333ZA
NL

Scientific

LUMC

Albinusdreef 2
Leiden 2333ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Dutch speaking

* 70 years of age

end stage renal disease (eGFR * 20 ml/min/1.73 m² (based on CKD-EPI))

Exclusion criteria

Illiterate

Unable to give informed consent

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 30-10-2018

Enrollment: 200

Type: Actual

Ethics review

Approved WMO

Date: 28-06-2018

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 09-10-2018

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 09-12-2019

Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Approved WMO
Date: 20-05-2020
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Approved WMO
Date: 17-10-2020
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20312
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL65322.098.18
Other	NL7104 (NTR7310)
OMON	NL-OMON20312

Study results

Date completed: 22-07-2022

Actual enrolment: 194

Summary results

Trial is ongoing in other countries