

Nephro-geriatric care pathway

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20312

Bron

NTR

Verkorte titel

POLDER

Aandoening

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

Nierziekten; Nierfalen; Geriatrie; Kwetsbaarheid; Dialyse

Ondersteuning

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

Overige ondersteuning: Nierstichting Nederland (Dutch Kidney Foundation)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 ≥ 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.

Doel van het onderzoek

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.

Onderzoeksopzet

T0: inclusion, T1: year 1

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Dutch speaking

>70 years of age

eGFR < 20 ml/min/1.73 m² (based on CKD-EPI)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Illiterate

Unable to give informed consent

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	30-10-2018
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 06-06-2018

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50178

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten