

DIALysis or not: Outcomes in older kidney patients with Geriatric assessment

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Nephrogeriatric assessment will be beneficial in identifying patients for whom conservative care might be a better option (QoL, clinical outcomes, costs) than starting dialysis.

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

Samenvatting

ID

NL-OMON28984

Bron

Nationaal Trial Register

Verkorte titel

DIALOGICA

Aandoening

End stage renal disease

Ondersteuning

Primaire sponsor: Leids Universitair Medisch Centrum

Overige ondersteuning: Leading the Change

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

QoL measured with CKD-PROMs (consisting of SF-12 and Dialysis Symptom Index)

Toelichting onderzoek

Achtergrond van het onderzoek

In 2016 almost 50% of the incident dialysis patients were >70 yrs of age. In this group, mortality in the first year is high (24%) and after 5 yrs 74% has died. Furthermore, there is an increasing percentage of patients withdrawing from dialysis treatment, and in dialysis patients >65 yrs withdrawal is with 30% the most prevalent cause of death since 2013. These data ask for a better identification of older patients for whom not starting dialysis but instead conservative care (CC) may be a better option than starting dialysis.

In the present project we aim to compare quality of life (QoL), clinical outcomes, and costs of CC and dialysis in older patients with ESRD, and aim to associate clinical and geriatric patient characteristics in the decision making trajectory with these outcomes, which could help to identify patients for whom CC might be a better option than starting dialysis.

Doel van het onderzoek

Nephrogeriatric assessment will be beneficial in identifying patients for whom conservative care might be a better option (QoL, clinical outcomes, costs) than starting dialysis.

Onderzoeksopzet

Once-yearly till end of follow up (depending on the moment of inclusion follow-up can vary from a minimum of 1 year to a maximum of 4 years)

Onderzoeksproduct en/of interventie

- Katz ADL-6
- Lawton iADL
- Hand grip strength
- Fall risk
- Montreal Cognitive Assessment (MOCA)
- Letter Digit Subtraction Test (LDST)
- 6-item Cognitive Impairment Test (6CIT)
- Geriatric Depression Scale (GDS-2; GDS-15 if positive)
- Optimism check
- Surprise question
- Clinical Frailty Score
- Charlson co-morbidity index
- Mini Nutritional Assessment (MNA)
- EQ5D-5L
- iMTA Costs
- Short Form-12 (SF-12)
- Dialysis Symptom Index (DSI)

- Decisional regret questionnaire

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age > 65 years
2. eGFR 10-20 ml/min/1.73m² (at least during 1 measurement in 3 months before inclusion)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Unwilling or unable to provide (written) informed consent
- Illiterate
- If a patient appears to be severely cognitive impaired after evaluation of the cognitive function, the patient will be consulted by a geriatrician for further clinical evaluation, such as the presence of dementia. In case of diagnosis of cognitive impairment, the geriatrician will judge if patient is mental competent ("wilsbekwaam") to provide informed consent to participate in the study. If not, the patient will not be prospectively followed and no blood sample will be collected.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	19-02-2020
Aantal proefpersonen:	1500
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:	05-02-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8352
Ander register	METC ZWH : 19 - 071

Resultaten