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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28984

Source
Nationaal Trial Register

Brief title
DIALOGICA

Health condition

End stage renal disease

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Leading the Change

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Clinical outcomes (independent functionality, hospitalisation, mortality), cost-effectiveness and decisional regret

Study description

Background summary

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.

Study objective

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

Study design

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)

Intervention

• Katz ADL-6
• Lawton iADL
• Hand grip strength
• Fall risk
• Montreal Cognitive Assessment (MOCA)
• Letter Digit Substraction 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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- 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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-02-2020
Enrollment:	1500
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	05-02-2020
Application type:	First submission

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	ID
NTR-new	NL8352
Other	METC ZWH : 19 – 071

Study results