

Geriatric assessments in older patients starting dialysis

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The primary objective of this study is to assess the association between pre-dialysis comprehensive geriatric assessment and early death or withdrawal from dialysis (

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON41575

Source

ToetsingOnline

Brief title

GOLD study

Condition

- Other condition
- Dementia and amnestic conditions
- Age related factors

Synonym

outcome, Quality of life

Health condition

Kwaliteit van leven

Research involving

Human

Sponsors and support

Primary sponsor: Dianet

Source(s) of monetary or material Support: Dianet

Intervention

Keyword: Comprehensive Geriatric Assessment CGA, Dialysis, Elderly

Outcome measures

Primary outcome

To assess the association between pre-dialysis comprehensive geriatric assessment and early death or withdrawal from dialysis (<6 months) after initiation of dialysis in patients aged over 65 years

Secondary outcome

The secondary objective of this study is:

To assess the association between pre-dialysis GA and dialysis-related complications in elderly patients

The tertiary objectives of this study are:

1. To describe the prevalence of geriatric syndromes in elderly patients starting dialysis
2. To describe the changes in cognitive function and functional status in the first 6 months after initiation of dialysis
3. To describe the association between pre-dialysis GA and quality of life, functional and/or cognitive decline 6 months after initiation of dialysis
4. To describe the caregiver burden after initiation of dialysis
5. To compare the quality of life, functional and cognitive status at baseline

and 6 months later of elderly patients starting dialysis and elderly patients choosing to forego dialysis treatment for whatever reason

6. To determine whether or not the success of dialysis and overall condition of the elderly patient was properly estimated by the nephrologist before the start of dialysis.

7. To assess how often falls occur within the six months period after initiation of dialysis in elderly patients (>65 years of age),

8. To describe what the sequelae of falls are in terms of fall-related injuries, emergency room visits, hospitalisation, fractures, care needs and functional decline in elderly patients starting dialysis

9. To assess what the incidence is of osteoporosis in this patient cohort and how the presence of osteoporosis contributes to injury risk after a fall (7.)

Study description

Background summary

The number of elderly patients with end-stage renal disease is increasing. Nephrologists and patients are faced with the dilemma of whether or not they should initiate dialysis. It is not yet known which older patients benefit from dialysis treatment and in which patients the disadvantages outweigh the advantages.

Study objective

The primary objective of this study is to assess the association between pre-dialysis comprehensive geriatric assessment and early death or withdrawal from dialysis (<6 months) in patients aged over 65 years

Study design

observational cohort study

Study burden and risks

There is no expected harm or benefit for the participating patients. The estimated time for the two interviews is 80 minutes. Besides a walking test will be applied (see E4)

Contacts

Public

Dianet

Brennerbaan 130
Utrecht 3524 BN
NL

Scientific

Dianet

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

1. Patients over 65 years old who initiate dialysis in one of the participating dialysis centra
2. Patients over 65 years old who are eligible for dialysis (according to their nephrologist) in

one of the participating dialysis clinics but deciding to withhold dialysis treatment

Exclusion criteria

Patients who do not understand or speak Dutch or English

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	05-08-2014
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO	
Date:	09-04-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	10-07-2014
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	13-10-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	04-11-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	24-03-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL47932.100.14