Implementation and evaluation of SDM in AKD

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21318

Source
NTR

Brief title
SHOUT-AKD

Health condition

CKD-KDIGO G4-G5A1-3

Sponsors and support

Primary sponsor: Santeon
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Patients' perceived level of involvement in the decision-making process (using the SDM-Q-9).

Secondary outcome

Patients' involvement in the decision-making process from the observers' viewpoint (using

the OPTION-5).

Study description

Background summary

The primary objectives are to assess the effectiveness of shared decision-making supported by outcome data; alongside its implementation in daily clinical practice. The secondary objectives are to assess the extent to which shared decision-making supported by outcome data leads to changes in the utilisation and outcomes of healthcare.

Study objective

The succesful implementation of shared decision making, supported by outcome measures, for treatment modality decisions in advanced kidney disease facilitates and improves this decisional process and the quality of delivered healthcare.

Study design

In total, all seven hospitals will participate in this trial for 20 months. In the first 6 months we will assess daily clinical practice in the hospitals with the aim to measure the current level of shared decision-making. Each month from May 2020 onwards, one hospital will make the transition, that will take approximately 1 month, to using shared decision-making supported by outcome data (see the description of the intervention), until all seven hospitals have implemented this in their daily clinical practice. Subsequently, for at least 6 months, we will assess the effectiveness and the extent to which shared decision-making supported by outcome data is implemented. Due to the stepwise design, some hospitals will be monitored longer before the transition, while others will be monitored longer after the transition, allowing us to make between-hospital comparisons. In each hospital 5 patients will be included per month. Patients included before and after the transition will receive a questionnaire and two follow-up questionnaires (after 6 and 12 months) to monitor patients' experiences in consultation, their daily functioning and other subjects related to the care they received. Also, in each hospital, 15 patients, both before and after the transition, will be asked permission to audio-tape consultations. These will be used to monitor the length of consultation and for two trained observers to assess shared decision-making supported by outcome data during consultation. Healthcare professionals will receive a questionnaire 3 months after the transition phase, to evaluate the effectiveness and extent to which shared decision-making supported by outcome data is implemented.

Intervention

Healthcare professionals, guiding patients facing the decision for a treatment modality in advanced kidney disease, will be introduced to a patient decision aid including (personalised) care outcomes, to support the process of shared decision-making. In addition, they will

receive a training on shared decision-making: they will be informed on the guiding principles, motivated to use shared decision-making in clinical practice, and taught how to apply it.

Contacts

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Eligibility criteria

Inclusion criteria

1) Patients with CKD-KDIGO G4-G5A1-3 kidney failure; 2) Having to make treatment modality decisions; 3) Age ≥ 18 years; 4) Understand the Dutch language in speech and writing; 5) Able to provide informed consent.

Exclusion criteria

1) Patients with dementia; 2) Patients that have already made treatment modality decisions and are being prepared for this treatment or are receiving this treatment.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2019
Enrollment:	630
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N.A.

Ethics review

Not applicable

Application type:	Not applicable

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	NL8376

Register ID

Other	MEC-U; Bureau Onderzoek en Innovatie, Santeon : W19.154 (MEC-U Nieuwegein); 2019-076 (Adviescommissie nWMO Martini Ziekenhuis Groningen)

Study results

Summary results

N.A.