Implementation and evaluation of SDM in AKD

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21318

Bron
NTR

Verkorte titel
SHOUT-AKD

Aandoening

CKD-KDIGO G4-G5A1-3

Ondersteuning

Primaire sponsor: Santeon
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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030-3073910

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders

Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2019
Aantal proefpersonen:	630
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N.A.

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL8376

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

Resultaten

Samenvatting resultaten
N.A.