Evaluation of Sexual , Fertility and Relationship Healthcare with chronic kidney patients and their partners

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

Summary

ID

NL-OMON43368

Source
ToetsingOnline

Brief title
SHaRE-Kidney

Condition

- Nephropathies
- Sexual function and fertility disorders

Synonym
fertility, relationship quality and the chronic kidney patient, Sexual function

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chronic Kidney Disease, Fertility healthcare, Relationship quality, Sexual healthcare

Outcome measures

Primary outcome

To obtain an insight in CKD patients* need and perspective on sexual and fertility care provided by renal care providers before and after kidney transplantation.

To obtain an insight in CKD patients* need and perspective on sexual and intimacy care provided by renal care providers during dialysis

Secondary outcome

- To determine which renal care provider should be accountable for providing sexual and fertility healthcare according to patients* point of view.

- To collect information on partner* perspective and opinions on sexual and fertility healthcare provided by renal care providers .

- To collect information on the influence of sexual dysfunction and fertility disorders on relationship quality.

Study description

Background summary

Sexual dysfunction (SD) and fertility disorders (FD) are common and underestimated problems in both men and women with Chronic Kidney Disease (CKD).
Kidney transplantation prolongs the life of CKD patients and will improve in sexual health, fertility, and energy. However, after transplantation the prevalence of SD still remains 46% and female transplant recipients experience higher incidence of complications during their pregnancy. Unfortunately, sexual

health and fertility remain difficult subjects to discuss and are often ignored by renal healthcare professionals.

Study objective

The aim of our study will be to evaluate patients* perspective on sexual and fertility healthcare currently provided by renal care providers. Furthermore we will identify patients* wishes and views upon this important part of renal healthcare and the impact of SD and FD on relationship quality. Partners will be included as they suffer from the effects of CKD on patients* sexuality and fertility as well.

Study design

Data for this cross-sectional studie will be collected with the use of questionnaires. Two different questionnaires will be used; one evaluating the patients and one evaluating the partner. Structure and design of these questionnaires were derived from questionnaires used in previous studies performed by our research institute. These questionnaires were designed to evaluate sexual function, fertility and impact of both items on relationship quality and quality of life in patients. Data will be processed an analysed anonymously.

Study burden and risks

Patients will receive an information letter by mail, explaining the objectives of the study. An informed consent form will be added with this letter. Participation can be considerate at home, without any haste. If consent is provided, a questionnaire will be send to the respondents.
It concerns a patient (and partner) survey with sensitive questions. Due to the fact the surveys consist of multiple questions (77 items for patients and 51 items for partners) it will require time to fill in the questionnaire. The questionnaires used in the second survey consist of 63 (patient) and 42 (partner) items.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- CKD patients who received a kidney or kidney/pancreas transplant in the last two years at the Leiden University Medical Centre
- Partners of CKD patients who received a kidney or kidney/pancreas transplant in the last two years at the Leiden University Medical Centre
CKD patients who receive hemodialysis at the Leiden University Medical Centre, the Haga Hospital or at the Haaglanden Medisch Centrum
- Partners of CKD patients who receive hemodialysis at the Leiden University Medical Centre, the Haga Hospital or at the Haaglanden Medisch Centrum
- CKD patients who receive peritoneal dialysis at home and are under control at the Leiden University Medical Centre, the Haga Hospital or at the Haaglanden Medisch Centrum
- Partners of CKD patients who receive peritoneal dialysis at home and are under control at the Leiden University Medical Centre, the Haga Hospital or at the Haaglanden Medisch Centrum;- Age older than 18 years
- Both patients and partners must consent in order to be included in the study
- Ability to understand a questionnaire in Dutch

Exclusion criteria

- Patients who are mentally incompetent to give informed consent
- Age under 18
- Patients who passed away

- Patients who moved abroad

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2016
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	19-07-2016
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	16-11-2016
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	20-01-2017
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	24-01-2017
Application type:	Amendment

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

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	NL57606.058.16