Reducing renal function deterioration by means of increasing medication adherence, improving immunosuppressive drug exposure and supporting a healthy lifestyle - an implementation study

Gepubliceerd: 04-06-2018 Laatst bijgewerkt: 13-01-2025

We hypothesize that implementation of the new post-transplantation program will result in: - Decreased renal function decline (improved graft survival) - Improved medication adherence - Improved tacrolimus exposition - Improved feeling of...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20914

Bron
NTR

Verkorte titel
RRFD study

Aandoening

Renal transplantation Immunosuppressants Medication adherence e-Health Patient participation

Ondersteuning

Primaire sponsor: Leiden University Medical Center, Leiden, The Netherlands
Overige ondersteuning: Astellas Pharma, Leiden, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Reduced deterioration of kidney function: slope of renal function during 2 years lower in subgroup with >95% compliance than in subgroup with <80% compliance.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale

Over the last decades, novel immunosuppressive drug regimen have significantly reduced the incidence of acute graft rejection episodes after kidney transplantation. However, long-term graft survival has not improved concomitantly. The main causes of late graft loss are death with graft function (dominated by cardiovascular disease) and chronic allograft dysfunction (dominated by a complex interplay between immunological and non-immunological causes). The key of new technological and scientific developments is to enhance personalized treatment regimens in order to meet each patient’s specific health needs.

Objective

For this purpose we plan to develop and introduce a personalized multi component care program aimed at prevention or postponement of progressive deterioration of kidney functioning. Recently, a medical dashboard (a ‘Shared Care Record’ to which all kidney patients and their treating physician(s) have access) was implemented in our regular outpatient care, including: 1. laboratory results, 2.results of self-monitoring by the patient regarding blood pressure, body weight and 3. e-coaching to optimize communication between patients and doctors. Using the medical dashboard is expected to increase patients’ active participation in their care. In addition to the general medical dashboard, we plan to offer study participants the following:

• Improving (both intentional and non-intentional) compliance of patients by (a) improvement of knowledge and skills of the patient, (b) improving motivation, (c) offering practical tools, and (d) improving communication skills of involved health care practitioners

• Medication review by outpatient pharmacy

• Use of Dried Blood Spot Technology for at-home based eAUC-monitoring (to obtain optimal immunosuppressive drug exposure)

• Option of participation in a life-style program (exercise / nutrition)

• Additional medical dashboard features, being a personal care plan addressing personal goals and concerns regarding compliance and optional e-modules that support patients in adopting and maintaining a healthy life-style.

Study design

Single center implementation study.

Study population

Renal transplant recipients, > 1 year post kidney(-pancreas) transplantation, CKD-EPI > 25 ml/min and using long-acting calcineurin-inhibitors. We target to include at least 100 patients.

Intervention

In addition to regular care, we will implement a program offering Dried Blood Spot monitoring of immunosuppressive drug exposure (AUC) at home, pharmacist led medication reviews, immunosuppressive medication reminders and a multicomponent lifestyle program aimed at improving cardiovascular renal profile.

Baseline measurement

Two months before the start of the intervention, baseline data concerning adherence will be collected through electronic monitoring of medication intake by using a smart dispenser (Sensemedic).

Main study parameters / endpoints

All participants will be followed during 2 years. The primary endpoint is reduction in renal function deterioration. Secondary endpoints are improvement of compliance to immunosuppressive medication, the feasibility of Dried Blood Spot home-blood sampling and clinical (biomarkers of renal function/damage, blood pressure and weight), immunological, cardiovascular, lifestyle and psychological parameters.
Furthermore a process-evaluation will be performed.

Nature and extent of the burden and risks as well as benefits associated with participation

The burden includes

- 2 pulse wave velocity measurements, one at baseline and one after 24 months.

- 2 iohexol measurements, one at baseline and one after 24 months. For these measurements, iohexol is injected through a Venflon. Within 4 hours from injection, 4 blood samples are taken. If possible, the iohexol measurement at baseline will be performed parallel to hospital AUC measurement.

- 3 additional AUC measurements by means of a Dried Blood Spot (DBS) procedure. Per DBS measurement, 3 capillary punctions need to be performed at home over the course of 3 hours.

- Completing questionnaires at baseline, 12 months and 24 months.

Concerning benefits:

- Patients receive 2 medication reviews aimed at improving understanding of and satisfaction with their medication

- Patients have the option to participate in a lifestyle intervention program

- Patients need to spend less time in the hospital, as the hourly blood drawings for determination of tacrolimus exposition (AUC) can now be performed at home

- Due to the more frequent performance of the AUC measurements at home, tacrolimus dose can be optimized

- Patients receive reminders to take their immunosuppressive medication

Doel van het onderzoek

We hypothesize that implementation of the new post-transplantation program will result in:

- Decreased renal function decline (improved graft survival)

- Improved medication adherence

- Improved tacrolimus exposition

- Improved feeling of patient autonomy, with increased patient satisfaction.

- Reduced (cardiovascular) co-morbidity / mortality

Onderzoeksopzet

All outpatient clinic visits take place at the LUMC

Frequency: every 3 months (according to standard care)

Medical checks: according to standard care

Extra care of study group:

- Medication review

o By pharmacist (once a year)

- Offering practical tools for medication intake (stepwise introduction).

o Medication box

o Daily automatic reminder

o Warning in case medication has not been taken within 4 hours from regular time.

- Life style support (optional)

o Activity monitor and/or

o Diet journal and/or

o Support by lifestyle coach and/or

o Urine analysis

- AUC-monitoring by means of Dried Blood Spot measurements

o Every 6 months

Clinical visits at nephrologist

o See above: guided by information from the medical dashboard, the following subjects will be discussed.

o Results

o At home measurements

o Medication

Visits at research nurse (t=0, t= 1 year and t= 2 years)

o At the same time as outpatient clinic visit (with nephrologist)

o T= 0 year:

Performing medical checks

Discussing medication on the basis of the Medical Dashboard

Electronic Blistering:

• Explanation (return blisters, do not throw away)

• Distribution of medication (at hospital pharmacy)

o T= 1 year: performing medical checks

o T= 2 year: performing medical checks

Visit to clinical pharmacist

o In month 10 and month 25: medication review.

o At same days as regular visits

Visit to lifestyle coach

o One face to face contact for every participant to discuss importance of cardiovascular renal risk profile for survival of graft; what can be done to improve/maintain current profile?

o Patients themselves decide whether or not they like to use (part of) the lifestyle intervention. Follow-up appointments will be video consults. (maximal 3 reimbursable hours a

year for a coach)

Onderzoeksproduct en/of interventie

There are 3 interventions:

1. Interventions to help improve compliance

2. At home monitoring of immunosuppressive drugs

3. Lifestyle program (optional)

1. Improvement of compliance (stepwise additional effect of different tools):

o App with medication alarm (MedApp)

o Medication review via pharmacist

o Feedback when medication is administered four hours too late through smart medication dispenser (Sensemedic).

2. Monitoring of immunosuppressive drugs

o Via Dried Blood Spot technology technique (in the first place measurement of tacrolimus, but measurement of other immune suppressive therapy is also possible)

3. Lifestyle modules (optional) with/without support

o Nutrition

o Physical Exercise

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- > 1 year after kidney(-pancreas) transplantation

- Follow-up visits take place in LUMC

- Creatinine clearance (CKD-EPI > 25 ml/min)

- Immunosuppressive regimen based on tacrolimus*

* Based on equivalence, in standard care both short-acting tacrolimus (Prograf twice daily dosing) and long-acting tacrolimus (Advagraf once-daily dosing) are prescribed. In order to compare results concerning AUC's (by Dried Blood Spot technology) and compliance, patients taking short-acting tacrolimus will be switched to long-acting tacrolimus.

- Sufficient mastery of Dutch

- Access to and capacity to use the internet.

- Availability of a mobile phone (necessary for receiving messages from smart medication dispenser)

- Informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- No internet access

- Creatinine clearance (CKD-EPI ≤ 25 ml/min)

- Insufficient knowledge of Dutch language

- Known previous allergic reaction to iodine and/or contrast fluid, as this potentially may trigger an allergic reaction after intravenous iohexol admission.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2017
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-06-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50600
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7051
NTR-old	NTR7256
CCMO	NL58000.058.16
OMON	NL-OMON50600

Resultaten