Samenstelling van lymfklieren en het risico op afstoting na niertransplantatie.

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The phenotypical and functional capacities of lymph node derived lymphocytes correlate better with biopsy-proven acute rejection after kidney transplantation than peripheral blood derived cells.

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

Samenvatting

ID

NL-OMON22565

Bron
Nationaal Trial Register

Verkorte titel
LAMBADA

Aandoening

niertransplantatie, kidney transplantation
lymfklieren, lymph nodes
alemtuzumab
alloreactiviteit, alloreactivity
veroudering immuunsysteem, ageing of the immune system
T-folliculaire helper cellen, T-follicular helper cells

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: Erasmus Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of this study is to determine the prognostic characteristics for BPAR in the first three months after kidney transplantation, as assessed in the lymphocyte composition of the lymph node in immunologically high-risk kidney transplantation.

Toelichting onderzoek

Achtergrond van het onderzoek

The composition and function of lymphocyte subsets in the peripheral blood poorly correlate with clinical outcomes like biopsy-proven acute rejection (BPAR). Lymph nodes differ in lymphocyte composition and contain for example more follicular T-helper cells and less cytotoxic CD4+ T cells than peripheral blood.

It is known that the migration of antigen presenting cells from the allograft to the draining lymph nodes is essential for the initiation of the alloreactive T-cell response and subsequent rejection. Therefore, the lymph nodes may be a better site than the peripheral blood compartment to study cells involved in allograft rejection.

We would like to investigate whether the phenotypical features and functions of lymph node derived lymphocytes are associated with BPAR. To this aim a locoregional lymph node will be harvested during kidney transplantation and compared to the peripheral blood sample before surgery. Differences in lymph node derived versus peripheral blood derived lymphocytes have not been studied so far in patients with renal failure before the start of immunosuppressive medication.

To study lymphocellular composition and risk of BPAR, a patient cohort with a relative high risk of BPAR is warranted: patients with PRA >6% and/or >3 HLA mismatches on A, B and DR will be included.

In this study we will focus on ageing of the immune system and on T-follicular helper cells.

In a substudy the composition of lymph nodes after alemtuzumab induction therapy administered three weeks before ABO-incompatible kidney transplantation and its effect on BPAR will be studied.

Doel van het onderzoek

The phenotypical and functional capacities of lymph node derived lymphocytes correlate better with biopsy-proven acute rejection after kidney transplantation than peripheral blood derived cells.

Onderzoeksopzet

t=0 kidney transplantation

t=3 months, window for BPAR

Onderzoeksproduct en/of interventie

harvesting of locoregional lymph node during kidney transplantation.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet the following criteria:

- Adult patients receiving a deceased or living kidney transplant in the Erasmus Medical Center Rotterdam, The Netherlands and:

- Group 1:

o Historical PRA > 6% and/ or:

o HLA MM ¡Ý4 on A, B and DR loci

- Group 2:

o Recipients of an ABO-incompatible kidney graft.
Patients have to give written informed consent to participate in the study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- ABO-compatible HLA identical living-related transplant recipients.

- Patients unable to give written informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	24-08-2015
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-01-2016
Soort:	Eerste indiening

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	NL5505
NTR-old	NTR5640
Ander register	: MEC-2015-301

Resultaten