Samenstelling van lymfklieren en het risico op afstoting na niertransplantatie.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22565

Source
Nationaal Trial Register

Brief title
LAMBADA

Health condition

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

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Erasmus Medical Center

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

- to capture global composition of lymph node versus blood leukocyte subsets in renal insufficiency.

- to compare the immunological ageing profile of T cells in the peripheral blood to the T cells derived from the lymph node.

- to assess whether pre-transplant frequencies of lymph node derived TFH, T and B cells predict BPAR.

- to assess differences in lymphocyte composition of lymph nodes in alemtuzumab treated versus untreated patients both in single cell suspension and within the tissue. (ABO-incompatible kidney transplant recipients receive alemtuzumab induction therapy three weeks before transplantation).

Study description

Background summary

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.

Study objective

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.

Study design

t=0 kidney transplantation

t=3 months, window for BPAR

Intervention

harvesting of locoregional lymph node during kidney transplantation.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-08-2015
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-01-2016
Application type:	First submission

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	NL5505
NTR-old	NTR5640
Other	: MEC-2015-301

Study results