Intrarenal T cells & chronic kidney graft rejection; the ITHACA study

Published: 24-06-2019
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The objective is to characterize intrarenal T cells isolated from transplant biopsies both phenotypically and functionally.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON52370

Source
ToetsingOnline

Brief title
ITHACA

Condition

- Other condition

Synonym
anti-donor immunity, chronic kidney allograft rejection

Health condition

orgaantransplantatie

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Nierstichting

Intervention

Keyword: biopsy, chronic rejection, kidney allograft, T cells

Outcome measures

Primary outcome

The main study parameters will be the number and characterization of intrarenal

T cells in cases of chronic kidney allograft rejection.

Secondary outcome

Intrarenal T cells isolated from cases with chronic rejection will be compared

to those isolated from individuals with chronic interstitial fibrosis without

evidence for rejection.

Study description

Background summary

The number of patients reaching end-stage renal disease requiring renal replacement therapy grows every year. Kidney transplantation is the preferred option in these patients but donor organs are scarce. After kidney transplantation, the most frequent cause of progressive loss of the transplant is chronic rejection. Recent studies have shown that the cellular part of the immune system is involved and the degree of intrarenal inflammation is the dominant predictor of graft loss. Previous research of our group showed that so-called T cells are involved but further functional characterization of these cells is needed to understand their nature and possible therapeutic options.

Study objective

The objective is to characterize intrarenal T cells isolated from transplant biopsies both phenotypically and functionally.

Study design

Recipients of a kidney transplantation undergoing a diagnostic renal biopsy will have an extra biopsy. The tissue obtained from this extra biopsy will be processed to obtain a single cell population. The individual cells (T cells,

other immune cells, endothelial cells, renal cells) will be characterised by flow cytometry and T cells will be isolated for functional characterization. The functional test of these cells will include the assessment of the reactivity to donor cells and their capacity to promote fibrosis.

Intervention

A diagnostic kidney biopsy procedure will be performed and in addition an extra biopsy will be taken for research purposes.
In addition, the patients will be asked to give 50 ml of heparin blood to obtain mononuclear cells from, needed to perform the functional assays.

Study burden and risks

The burden and risks associated with participation are related to the extra renal biopsy. The kidney transplant is located superficially in the ileac fossa and can be easily accessed for renal biopsy with adequate local anaesthesia. Therefore, the procedure is not considered painful by patients and the risk for bleeding is very low. This procedure is performed frequently (>400 times per year) at the radiology department of the Erasmus MC.

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

-18 years and older
-able to give informed consent
-clinical diagnosis of chronic rejection for which a renal biopsy is indicated for confirmation

Exclusion criteria

-known extra risk for bleeding (e.g. clotting disorder or medication)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-01-2020
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	24-06-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-10-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL69727.078.19