Prospective study to evaluate trained immunity in kidney transplantation

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

Summary

ID

NL-OMON53183

Source
ToetsingOnline

Brief title
PROTEKT

Condition

- Other condition

Synonym
graft survival, kidney transplantation

Health condition

niertransplantatie

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,National Institute of Allergy and Infectious Diseases (NIAID);USA

Intervention

Keyword: gene expression, kidney transplantation, rejection, trained immunity

Outcome measures

Primary outcome

1. The trained immunity profile of monocytes from renal transplant patients.

Before, one week after, and three months after renal transplantation, blood is drawn from patients and circulating monocytes are isolated to examine the activity, transcriptome, and epigenome of these monocytes.

2. The association between trained immunity and renal transplant survival.

The association between the trained immunity profile as measured in (1) and graft survival in the first two years after transplantation is investigated.

Secondary outcome

1. The association between trained immunity and inflammation and tissue damage.

The association between the trained immunity profile as measured in (1) and markers for tissue damage and systemic inflammation is investigated.

2. The association between trained immunity and the concentration of immunosuppressive drugs in the blood of patients.

3. The association between trained immunity and the amount of white blood cells

and subsets of white blood cells.

Study description

Background summary

Kidney transplantation is an important treatment for renal failure. To enable kidney transplantation and prevent rejection, immunosuppressive mediation is needed. This medication is now mainly directed at cells of the adaptive immune system (T and B cells). However, cells of the innate immune system also play an important role in transplant immunology. In this study, we investigate trained immunity in kidney transplant patients. Trained immunity is a form of memory of innate immune cells, which causes higher inflammatory activity upon stimulation. Our hypothesis is that trained immunity may lead to activation of the immune response against the graft and have negative effects on graft survival.

Study objective

In this study, we therefore aim to investigate how trained immunity is systemically regulated in kidney transplant patients and how the degree of trained immunity affects graft survival in patients. A better understanding of these processes contributes to the discovery of new targets for therapy for transplant patients, which could increase graft survival.

Study design

This is a clinical observational study.

Study burden and risks

It is an observational study in which participants donate blood. In our opinion, there are no risks associated with this. The burden or participating in this study is minimal.

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

Kidney transplant recipient
Age 18 - 80 years

Exclusion criteria

No informed consent
Infection in the past four weeks

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-12-2023
Enrollment:	100
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	15-05-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	19-08-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL84277.091.23