Characterisation tissue-resident cells in donor and native kidneys

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

Summary

ID

NL-OMON49133

Source
ToetsingOnline

Brief title
CHATCKID

Condition

- Other condition

Synonym
transplant failure

Health condition

orgaantransplantatie

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: native kidney, tissue-resident immune cells, transplanted donor kidney

Outcome measures

Primary outcome

The primary study parameter comprises of the development of a method for eventually obtaining large numbers of intrarenal immune cells from a kidney biopsy.

Secondary outcome

The secondary outcome of this study consists of the comparison of both phenotype and function of immune cells obtained from a failed renal allograft to that obtained from a healthy piece of the native kidney.

Study description

Background summary

Kidney transplantation is the preferred type of renal replacement therapy for patients suffering from end-stage renal disease. However, long-term renal allograft survival is compromised by chronic rejection, being one of the most frequent causes of progressive loss of renal allograft function.
Recent studies have revealed that the cellular part of the immune system is involved and the degree of inflammation is the predominant predictor of graft loss. Little is known with respect to which immune cells and mechanisms eventually contribute to loss of the renal allograft.
Large numbers of intrarenal immune cells need to be obtained for detailed characterization of phenotype and function of immune cells within the graft
Different methods for obtaining immune cells will be compared with respect to yield using renal tissue obtained from failed renal allografts and healthy native kidney tissue. In addition, phenotype as well as function of immune

cells of failing renal allografts will be compared to that of healty native kidneys.

Study objective

The primary objective of this study is to develop a method by which large numbers of immune cells can eventually be obtained from a kidney biopsy to study phenotype and function of immune cells and unravel mechanisms contributing to loss of renal allograft function.
For this, we will use kidney tissue obtained from a failed renal allograft and native kidney and compare yield of immune cells for different methods. In addition, we will compare phenotype and function of immune cells present within a failed renal allograft to immune cells present within a healthy piece of the native kidney.

Study design

Subjects undergoing a transplantectomy or nephrectomy, will be asked to give informed consent for using part of their transplanted/native kidney and one additional blood donation for scientific research.
Different methods will be compared with respect to yield of intrarenal immune cells. One of these methods uses peripheral blood mononuclear cells of the patient to induce proliferation of intrarenal immune cells.
In addition, phenotype and function of the obtained immune cells isolated from a failed renal allograft will be compared to that from a piece of healthy native kidney.

Study burden and risks

For this research we will make use of (remaining) kidney material obtained following a transplantectomy or nephrectomy and one additional blood donation (2 heparin tubes a 10 mL blood=20 mL of blood) at the time of routine blood withdrawal by experienced personnel.
The burden for the patient is therefore minimal and no additional risks are involved when participating in this study.

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
-undergoing a transplantectomy or nephrectomy

Exclusion criteria

-younger than 18 years
-undergoing a nephrectomy due to an inflammatory condition

Study design

Design

Study type:	Observational invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-01-2021
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	11-11-2020
Application type:	First submission
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	NL74695.078.20