Incidence and outcome of antibody-mediated rejection in immunological high-risk renal transplantation: An observational PROCARE 2.0 study

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To determine 1) the incidence of ABMR and mixed ABMR / T cell-mediated rejection (TCMR) in immunological high-risk kidney transplant recipients treated with the currently prevailing immunosuppressive regimens, 2) to relate ABMR and mixed-type...

Ethical review	Approved WMO
Status	Pending
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational invasive

Summary

ID

NL-OMON52238

Source
ToetsingOnline

Brief title
PROCARE 2.0

Condition

- Renal disorders (excl nephropathies)

Synonym
humoral rejection

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Chiesi Farmaceutici,Nierstichting

Intervention

Keyword: humoral rejection, immunological risk, kidney transplantation

Outcome measures

Primary outcome

The main study endpoints are the incidence of ABMR, the incidence of mixed ABMR/TCMR, and kidney function after at least one year of follow-up.

Secondary outcome

In addition, the immune system will be mapped with a focus on B cell function, the development of (non-)HLA antibodies, the interaction between B cells and T follicular helper cells, and complete immune phenotypic profiling.

Study description

Background summary

Despite improved patient and graft survival of kidney transplant recipients, as much as 20% of these patients will again reach end-stage kidney disease within 5 years after transplantation. Antibody-mediated rejection (ABMR) is one of the major causes of early graft loss and perhaps even more important, of late deterioration of graft function.

Study objective

To determine 1) the incidence of ABMR and mixed ABMR / T cell-mediated rejection (TCMR) in immunological high-risk kidney transplant recipients treated with the currently prevailing immunosuppressive regimens, 2) to relate ABMR and mixed-type rejection to clinical outcome (graft survival, function, proteinuria, histology), and 3) to test novel state-of-the-art immunological assays in a clinical setting.

Study design

Prospective cohort study.

Study burden and risks

Limited benefits or risks are associated with participation in this study since this study is a prospective observational clinical cohort study and all patients will receive standard of care. The only possible adverse event will be mild discomfort or a local hematoma resulting from the venous puncture necessary for the drawing of blood.

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

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

- >=18 years old
- About to receive a deceased donor or living donor renal transplant
- Provide informed consent
- Immunological high risk for rejection
a. Luminex positive DSAs (Immucor background corrected MFI >500)8;
and/or
b. Re-transplantation with repeated mismatch; and/or
c. Husband to wife donation (after fathering children); and/or
d. Offspring to mother donation

The healthy subjects are the living donors of aforementioned patients, they have to meet the following criteria,
- >=18 years old
- About to donate a kidney as a living donor
- Provide informed consent

Exclusion criteria

A potential subject who meets the following criterium will be excluded from participation in this study:
- Regular follow-up after transplantation is not feasible
- AB0-incompatible or HLA-incompatible kidney transplantation

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2021
Enrollment:	300
Type:	Anticipated

Ethics review

Approved WMO Date:	01-09-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	25-05-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	03-03-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-04-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-04-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT05140018
CCMO	NL76773.042.21