ABO-incompatible kidney transplantation in The Netherlands.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27246

Source
Nationaal Trial Register

Brief title
TBA

Health condition

kidney transplantation

Sponsors and support

Primary sponsor: There is no funding. This is a investigator-driven study.
Source(s) of monetary or material Support: investigator-driven.

Intervention

Outcome measures

Primary outcome

The primary outcome is (uncensored) graft survival of ABO-incompatible kidney transplant recipients as compared to ABO-compatible control patients with a living donor.

Secondary outcome

Secondary outcomes include:
- Patient survival
- Renal function and proteinuria
- Infection
- Non-skin malignancy
- Renal allograft rejection
- Comparison with kidney transplant recipient with a postmortal allograft
- Comparison with kidney transplant recipients which an ABO-compatible donor via the national kidney exchange program

Study description

Background summary

Rationale
The ABO blood group system has been a historical barrier in kidney transplantation. By performing antibody removal techniques combined with induction therapy pioneering centers have shown that successful kidney transplantation is possible despite blood group incompatibility1-3. In 2006 the first ABO-incompatible kidney transplantation was performed in the Netherlands, adopting the Swedish protocol with immunoadsorption as antibody removal technique and the anti-CD20 monoclonal antibody Rituximab as induction therapy4. Since then, the proportion of ABO-incompatible kidney transplantation has increased in the Netherlands and it has become a routine procedure in most university hospitals. Adaptations of the protocol have been implemented, amongst others in induction therapy and number of immunoadsorptions. To assess the quality of care for ABO-incompatible kidney transplant recipients in the Netherlands, we would like to investigate outcomes after blood group incompatible kidney transplantation in all 6 university hospitals performing this type of transplantation. Its results are likely to guide future studies in this field and to develop guidelines for ABO-incompatible kidney transplantation.

Aim
The aim of this study is to determine the clinical outcomes of kidney transplant recipients with an ABO-incompatible donor in the Netherlands.
The primary outcome is (uncensored) graft survival of ABO-incompatible kidney transplant recipients as compared to ABO-compatible control patients with a living donor.
Secondary outcomes include:
- Patient survival
- Renal function and proteinuria
- Infection
- Non-skin malignancy
- Renal allograft rejection
- Comparison with kidney transplant recipient with a postmortal allograft
- Comparison with kidney transplant recipients which an ABO-compatible donor via the national kidney exchange program

Methods
This study is a retrospective analysis of all ABO-incompatible kidney transplantations performed in the Netherlands, starting March 2006 till January 2018.
Patients have given written informed consent to collect their clinical data on transplant outcomes to be registered in the NOTR (Nederlandse Orgaantransplantatie Registratie).
These data are compared to outcomes of recipients of an ABO-compatible kidney allograft.
These anonymous data are analyzed retrospectively using SPSS software.
Funding
This is an investigator-driven study. It has no funding.

Study objective

Outcomes after ABO-incompatible kidney transplantation are favorable compared to ABO-compatible deceased donor transplantation. Due to the desensitization procedure outcomes after ABO-incompatible kidney transplantation will differ from ABO-compatible living donor transplantations.

Study design

post transplantation outcomes.

Intervention

This is an observational study.

Contacts

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Eligibility criteria

Inclusion criteria

1. ABO-incomaptible and ABO-compatible kidney transplantations performed between March 2006 and January 2018.
2. CNI-based immunosuppresive therapy

Exclusion criteria

1. unknown maintenance immunosuppresive therapy.
2. age <16 years
3. unknown ABO status

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-03-2019
Enrollment:	10000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	05-03-2019
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	NL7587
Other	METC EMC : MEC-2018-1325

Study results