ABO-incompatible kidney transplantation in The Netherlands.

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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-…

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27246

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

kidney transplantation

Ondersteuning

Primaire sponsor: There is no funding. This is a investigator-driven study.
Overige ondersteuning: investigator-driven.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

post transplantation outcomes.

Onderzoeksproduct en/of interventie

This is an observational study.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	05-03-2019
Aantal proefpersonen:	10000
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	05-03-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7587
Ander register	METC EMC : MEC-2018-1325

Resultaten