

Alemtuzumab or rituximab induction in ABO-incompatible kidney transplantation.

No registrations found.

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

Summary

ID

NL-OMON28980

Source

Nationaal Trial Register

Health condition

ABO-incompatible kidney transplantation.

Dutch:

bloedgroep ABO-incompatible niertransplantatie.

Sponsors and support

Primary sponsor: investigator-driven

Erasmus Medical Center Rotterdam

Source(s) of monetary or material Support: investigator-driven

Erasmus Medical Center Rotterdam

Intervention

Outcome measures

Primary outcome

- To compare the number of biopsy-proven acute rejections (BPAR) within three months after

ABOi kidney transplantation in rituximab versus alemtuzumab treated patients.

Secondary outcome

- To compare infectious complications after ABOi kidney transplantation in rituximab versus alemtuzumab treated patients.
- To compare renal function one year after ABOi kidney transplantation in rituximab versus alemtuzumab treated patients.

Study description

Study objective

Alemtuzumab induction therapy in ABOi kidney transplantation lowers the incidence of cellular-mediated BPAR compared to rituximab induction, without affecting the number of antibody-mediated rejections.

Study design

t=0

t=3 months

t=12 months

Intervention

observational study

Contacts

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Eligibility criteria

Inclusion criteria

Recipients of an ABO-incompatible kidney transplant aged 18 years or older.

Exclusion criteria

Recipients of an ABO-compatible kidney allograft.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	30-04-2015
Enrollment:	100

Type: Anticipated

Ethics review

Positive opinion

Date: 02-06-2015

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	NL5268
NTR-old	NTR5384
Other	: MEC-2015-246

Study results