The relevance of donorspecific memory B cells in immunised kidney transplant recipients

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The objective of the current study is to determine whether the presence of donor-specific B cell memory determines whether a patient will develop graft rejection or inferior graft function, especially in kidney transplant recipients who have donor-...

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

Summary

ID

NL-OMON39729

Source
ToetsingOnline

Brief title
Donorspecific memory B cells in kidney transplantation

Condition

- Other condition
- Nephropathies

Synonym
End-stage renal failure, kidney transplantation

Health condition

orgaantransplantatie

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Nierstichting Nederland

Intervention

Keyword: ELISPOT, humoral immunity, kidney transplantation, rejection

Outcome measures

Primary outcome

The main parameter to be assessed in the current study is the frequency of donor-specific memory B cells as determined by a novel ELISPOT based technique. Furthermore, donor-specific antibody levels will be determined by CDC and Luminex techniques.

Secondary outcome

The secondary study parameters are clinical parameters. The transplant function at 6 and 12 months will be determined by using the estimated Glomerular Filtration Rate (eGFR). Furthermore, the occurence of cellular and antibody mediated rejection within the first year after transplantation will be recorded,

Study description

Background summary

Determining the risk of rejection prior to organ transplantation is an important aspect of the transplant procedure, especially in immunised patients. Historically, donor-specific antibodies are detected in the serum of the patient by using a complement dependent cytotoxicity (CDC) assay. This assay has been used ever since to prevent hyper-acute rejection. Recently, novel techniques for the detection of donor-specific antibodies have been introduced, based on the binding of antibodies to synthetic HLA molecules on polystyrene

beads (Luminex). Although this technique is much more sensitive in detecting donor-specific antibodies, the clinical relevance of the detected antibodies is currently unknown. In some patients the presence of antibodies only detected by Luminex is associated with early rejection, while in others no negative effect of these antibodies are observed. We hypothesise that the presence of donor-specific memory B cells underlies this divergence. We have recently developed a novel technique to determine the frequency of HLA-specific memory B cells in the circulation of transplant patients and will use this technique to determine the donor-specific B cell load in immunised transplant recipients.

Study objective

The objective of the current study is to determine whether the presence of donor-specific B cell memory determines whether a patient will develop graft rejection or inferior graft function, especially in kidney transplant recipients who have donor-specific antibodies only detectable with the Luminex technique.

Study design

The current study is a pilot study to determine whether the newly developed HLA-specific memeory B cell ELISPOT assay provides clinically useful information for risk assessment of (immunised) kidney transplant recipients.

Study burden and risks

There are no risks involved in participation in this study. There are also no direct benefits for the participating patients.

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

Kidney transplant recipients who receive a kidney transplant after having rejected their previous transplant. Additionally, thier kidney donors in case of living donor transplantation.

Exclusion criteria

Subjects infected with HIV or Hepatitis C

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2013
Enrollment:	120

Type:	Actual

Ethics review

Approved WMO Date:	02-04-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	17-09-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL42616.058.12