Influence of haemodialysis on the in vitro mitogenic function and interferon-gamma production of the CD4- and CD8-positive T-lymphocytes in patients undergoing chronic heamodialysis

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To determine the general usefulness of and a proper moment when blood should be taken for the in vitro IFN-γ assays in patients undergoing chronic haemodialysis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ancillary infectious topics
Study type	Observational invasive

Summary

ID

NL-OMON33618

Source
ToetsingOnline

Brief title
Haemodialysis and T-lymfocyte mitogenic function

Condition

- Ancillary infectious topics
- Nephropathies

Synonym
immunity, resistance

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cytomegalovirus, hepatitis B, interferon-gamma, latent tuberculosis

Outcome measures

Primary outcome

To identify the possible differences (intrapersonal variability) in the

proliferative function of:

- T-lymphocytes generally (using the phytohemaglutinine tube)

- TB-specific lymphocytes (using the Quantiferon-GIT test)

- CMV-specific lymphocytes (using the Quantiferon-CMV test)

- HB-specific lymphocytes (using the Quantiferon-HB)

between the blood samples which were drawn before, during and after the same

hemodialysis.

Secondary outcome

1. differences in the proportion of patients with indeterminate test result in

the positive controle tube (phytohaemaglutinine) in the haemodialysis, PD,

non-haemodialysis renal failure and control groups

2. differences in the proportion of patients with positive Quantiferon-CMV test

in the hemodialysis, PD, non-HD renal failure and control groups

3. differences in the proportion of patients with positive Quantiferon-HB test

in the hemodialysis, PD, non-HD renal failure and control groups

4. differences in the proliferative capacity measured as the amount of produced

IFN-γ in the positive controle tube between the group of patients with

hemodialysis, PD, non-HD renal failure and control group

Study description

Background summary

In vitro interferon-gamma (IFN-γ) assays are able to quantitatively measure the IFN-γ production by the sensitized T-lymphocytes (CD4 of CD8-positive) as response to the specific antigen(s) they previously have been sensitized with (as a result of natural infection or vaccination). Various antigens can be used for the T-lymphocyte in vitro stimulation. The usefulness of the in vitro IFN-γ assays has extensively been tested to diagnose latent tuberculosis. The response to the other antigens such as cytomegalovirus (CMV) and hepatitis B (HB) antigens can also be determined. To obtain the reliable results it is necessary that the proliferatieve T-lymphocyte function is normal.
Haemodialysis patients are at increased risk for the infectious complications. There are many clinical situations where in vitro IFN-γ assay could be implied to determine the etiology of the infection, to start the pre-emptive therapy or to assess the effectivity of the vaccination.
However, the important missing information is the influence of the hemodialysis on the proliferative function of the T lymphocytes which could increase the frequency of the indeterminate results if blood is not drawn at the proper moment with regard to the dialysis session.

Study objective

To determine the general usefulness of and a proper moment when blood should be taken for the in vitro IFN-γ assays in patients undergoing chronic haemodialysis.

Study design

This study will be a cross-sectional study, with 4 groups of patients.

The following procedures will be performed:
I. Patients treated with haemodialysis (group A):

- intravenous blood will be collected before, 30 minutes after the start and at the end of the same haemodialysis, 5 tubes will be filled at each time point, each with 1 milliliter blood.
II. Patients treated with peritoneal dialysis, patients with renal insufficiency but no renal replacement therapy and healthy controls (groups B, C, D):
- intravenous blood will be collected once (cca 20 ml blood) between 8 and 12 a.m.

The five blood tubes will be used to perform the next tests:
- Quantiferon-GIT test tube (tuberculosis antigens),
- Quantiferon-CMV test tube (CMV antigens),
- Quantiferon-HB test tube (hepatitis B antigens),
- positive controle tube (phytohaemaglutinine as a mitogen),
- negative controle tube (no mitogen added).

After performing the QuantiFERON-GIT and Quantiferon-CMV and -HB tests the tubes will be stored at -20o degrees Celsius for 5 years at the Laboratory of Virology of the UMCU.

Study burden and risks

The burden associated with the participation is low (three venapunctures), the risks of the participation are the same as the risk of the venapuncture

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

group A - renal failure, haemodialysis
group B - renal failure, peritoneal dialysis
group C - renal failure, no dialysis

Exclusion criteria

group D - renal failure and/or immunocompromising condition or immunosuppressive medication

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-03-2008

Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	08-01-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-07-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-05-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL18453.041.07