the prevalence of APOL1 high risk alleles in dialysis population in the Netherlands

Published: 18-06-2020
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To investigate the prevalence of APOL1gene in patient on dialysis in the the Netherlands and correlate them to clinical parameters

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational invasive

Summary

ID

NL-OMON54657

Source
ToetsingOnline

Brief title
the prevalence of APOL1 in dialysis population

Condition

- Renal disorders (excl nephropathies)

Synonym
kidney failure, kidney insufficiency

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: winstreserve van F.J. Bemelman

Intervention

Keyword: apol1, dialysis, kidney failure, the Netherlands

Outcome measures

Primary outcome

the primary outcome is the proportion of two high risks alleles of APOL1 gene

in patients on dialysis in the Netherlands

Secondary outcome

The secondary outcome is the proportion of the two high risk alleles of APOL1

gene in patients on dialysis from Western Africa, Suriname, the Netherlands

Antilles and Moroccan and compare this to dialysis patients from Caucasian

background. In addition, the prevalence of kidney disease related monogenic or

polygenic mutations in the dialysis population of Amsterdam and Utrecht.

Study description

Background summary

Patients with African ancestors have increased risk of having progressive kidney disease. One of the possible explanations is the APOL1 (apolipoprotein 1) gene. There have been two high risk alleles (G1 and G2) identified which are associated with increased risk of non-diabetic kidney disease in African Americans in the United states of America. Carriers from these risk alleles have a 4 to 20-fold chance on end stage renal disease (ESRD). The risk of carriers on ESRD after kidney donation remains up to now speculative. In the United states of America APOL1 variants are relatively common in African Americans, but absent in patient from European descent. The prevalence of the risk alleles among the Caucasian European population is reported to be less than 1 %. However, in certain urban areas of the Netherlands, such as Amsterdam, a relatively large proportion of the chronic dialysis population has a non-Western background. The prevalence of the polymorphisms of the APOL1 gene in this population is unknown.
Renal transplantation remains the optimal treatment for most patients with renal failure. It increases patient survival, patient quality of live and reduces costs. In the Netherlands, renal transplantation with a donor organ from a live donor is common. More than 50% of all transplantations are performed with live donor organ, resulting in excellent outcomes.
However, no excess harm should be done to the donor. Removal of the donor

kidney and also late outcomes after transplantation should be as safe as possible. To this end candidate donors are meticulously screened and evaluated to make an accurate risk assessment. Up to now family members of non-Western background are approached by the donor team in a similar way as the Caucasian families when discussing the subject of organ transplantation and living donation.

Study objective

To investigate the prevalence of APOL1gene in patient on dialysis in the the Netherlands and correlate them to clinical parameters

Study design

A cross-sectional study

Study burden and risks

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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

all adults on dialysis with given informed consent

Exclusion criteria

all patients who dit not give informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-10-2020
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	18-06-2020
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-09-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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	NL69157.018.19
Other	NL8530