Identifying MicroRNA Biomarkers of Obesity-Associated Renal Disease after Living Kidney Donation

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON39270

Source
ToetsingOnline

Brief title
MicroRNA Biomarker of Obesity-Associated Renal disease

Condition

- Other condition
- Lipid metabolism disorders
- Renal disorders (excl nephropathies)

Synonym
Kidneyfailure, Obesity-Associated Renal Disease

Health condition

obesitas

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Nephrosearch subsidie (intern fonds)

Intervention

Keyword: Biomarkers, Living Kidney Donors, MicroRNA, obesity

Outcome measures

Primary outcome

The main outcome parameter will be a top-5 of differentially expressed miRs in plasma and urine between obese progressors to albuminuria versus non-progressors, adjusted for miRs associated with progression to albuminuria not related to obesity.

Secondary outcome

- albuminuria from 24h urine

- renal function as assessed by 24h urinary creatinine clearance

- anthropometric measures of obesity (BMI, waist/hip ratio)

- fasting glucose and post OGTT glucose

- automated blood pressure (dynamap)

- non-invasive assessment of microcirculation using orthogonal polarization spectral (OPS) imaging of oral mucosa.

- serum/plasma parameters of obesity-associated parameters of inflammation (hsCRP), endothelial dysfunction (sICAM-1, sVCAM-1, sE-Selectine) and coagulation (PA1-1)

- smoking history, alcohol use

- medication including hormonal replacement therapy in women

- medical history / record review for cardiovascular history and/or de novo

renal disease.

Study description

Background summary

Serious overweigt is one of the criteria that deem it unsafe to donate a kidney. This is due to the reason that among overweight persons the renalfunction may deteriorate more quickly after donation. At this moment the Body Mass Index or BMI is the best standard to estimate a serious overweight. A person is seriously overweight when his of hers BMI is higher than 30(kg/m2). However the BMI does not predict as well wich serious overweight is harmfull and wich are not. A certain number of people, who are seriously overweight may be perfectly able to donate a kidney safely, that is if we had a beter standard to asses the risk. With this study we hope to find this standard in the blood/urine. This is of great importance because the Dutch population is getting fatter and possible donors are getting more seriously overweight(30 kg/m2).

Study objective

We try to find a new standard within the field of ''MicroRNA'' proteins, that swim around in peoples blood and/or urine. MicroRNA's are very small proteins, that switches of genes in the cells, they are able to switch genes on/off. In this matter they control a lot of processes(of disease). With this research we hope te find a number of MicroRNA's that are involved with the arise of kindney damage in overweight people. MicroRNA's are measurable in the blood and in 24 hr urine. The MicroRNA's found may serve as a future standard to predict wich seriously overweight people are, and wich seriously overweight people are not, eligible to safely donate a kidney.

Study design

The study is a proof-of-principle study with an extreme phenotype nested case-control design. Identification of microRNAs in plasma and urine will be conducted in a cohort of former living kidney donors. All former donors are invited to standard post-donation control of their renal function, proteinuria, and blood pressure, and weight. During the clinical visit there will be 24h urine and blood of the participants to microRNA measure their profiles into fat and thin non-progressors and progressors of microalbuminuria since donation.

Figure 1
Urinary albumin excretion (UAE)
> 0.3g / d at follow-up BMI
18.5-25 kg/m2 BMI> 27 kg/m2

Progressor overtime 20-25
extremes 20-25 extremes
Non-Progressor overtime 20-25
extremes 20-25 extremes

Study burden and risks

A very low risk, taking blood may involve some inconvenience,

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 former living kidney donors who donated a kidney since 1968 at the Leiden University Medical Center (aproximate n<=650).

Exclusion criteria

Patients will be excluded from analyses if their medical history or the oral glucose tolerance test (OGTT) at the day of assessment reveals presence of diabetes mellitus.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2014
Enrollment:	650
Type:	Actual

Ethics review

Approved WMO

Date:	02-08-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.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	NL39603.058.13