Tubular and glomerular damage markers in urine and blood samples in diabetic patients.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Diabetic complications
Study type	Observational invasive

Summary

ID

NL-OMON32838

Source
ToetsingOnline

Brief title
Tubular and glomerular damagemarkers

Condition

- Diabetic complications
- Nephropathies

Synonym
diabetic nephropathy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: PREVEND

Intervention

Keyword: diabetes mellitus, glomerular damage markers, tubular damage markers

Outcome measures

Primary outcome

Study parameters are the concentration tubular and glomerular biomarkers and

urine albumin excretion.

Secondary outcome

association with renal function (measured as eGFR)

association with diabetes control (measured as HbA1c)

Study description

Background summary

Tubular damage markers in urine and blood samples of diabetes mellitus patients

Their is a need for markers that reliably predict the progression of renal diseases. Macro-albuminuria is at this moment the best predictor for future decrease in renal function. Nevertheless, a part of patients with macro-albuminuria does not get decline in renal function, where an other part of patients with micro-albuminuria does decline in renal function.
A lot is yet unknown about the exact cause of albuminuria. It is not clear whether albuminuria is caused by tubular or glomerular damage. When the glomerulus is damaged, large proteins that normally would not be able to reach the pre-urine, are being filtrered through de glomerular membrane. Certainly when these large proteins are negatively charged, they shouldn't be filtrated, because the glomerular membrane is also negatively charged. Presence of for example IgG4 in urine is indicative of glomerular damage.

Recenty a number of urinary tubular damage markers have been discovered. Some of these markers are located in the proximal tubulus in the cell cytoplasm, lysosomes or the brush border. Other markers are located in the cytoplasm of distal tubulus cells. These markers are in healthy persons not to be found (or in very small quantities) in urine. Presence of these markers in urine is indicative of renal tubular damage.

A lot is unclear about in what situation these markers are increased and what it actually means. This is why in this study patients with diabetes mellitus with different extent of renal damage are investigated at these biomarkers.

Study objective

The primary question is whether certain tubular biomarkers are associated with albuminuria. It is thougt that to much albumin in the pre-urine is toxic to the proximal tubulus. By measuring different kind of damage markers of different locations of the nephron, it can be determined to what extent albumin is toxic to the tubulus.

Study design

This is a cross-sectional study, where 100 patients witg diabetes mellitus are invated to participate. They are invated to visit the out-patient clinic to hand over some urine and undergo a venapuncture to obtain some serum. Patients are beforehand selected on the amount of albumin in their urine during their last visit.
40 patients with normo-albuminuria, 40 patients with micro-albuminuria and 20 patients with macro-albuminuria are to be included.
Patients with micro- and macro-albuminuria are checked (in their medical file) for retinopathy, to be sure that the albuminuria is the consequence of diabetes. The samples are collected within 3 months.

In the urine samples 9 biomarkers, albumin and creatinine are measured. In the blood samples will besides these 9 biomarkers also be measured albumin, BUN, creatinin, glucose and HbA1c.
The first morning void is requested. For this all participants get by mail a cup. Also inspection in the medical file is requested.

The researchers like to keep the option open to adress the same patients after a few years. The urine and blood samples are also kept in the fridge for maximum one year to measure new biomarkers if available.

Study burden and risks

The burden to participants is a sole extra visit to the out-patient-clinic. A venapuncture is done and 20 cc of blood are taken. Risk of the venapuncture is a local haematoma. Also patients are required to collect their first morning void.

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

age > 18 years
diabetes mellitus
albuminuria (40 patients with normo-albuminuria, 40 with micro-albuminuria and 20 with macro-albuminuria will be included)

Exclusion criteria

lacking retinopathy when having albuminuria (micro or macro)
primary renal disease other than diabetic nephropathy
mentally incapacitated
erythrocyturia (more than 25 per field of vision)

Use of nephrotoxic medication

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-03-2009
Enrollment:	100
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	18-12-2008
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL24774.075.08