Plasma oxalate and glycolate levels in patients with chronic kidney disease (CKD stage 4 and 5).

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The aim of this study is to establish reference values for plasma oxalate and plasma glycolate levels in patients with chronic kidney insufficiency. Values in patients with PH and secondary hyperoxaluria will be compared to values measured in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metabolic and nutritional disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON52424

Source
ToetsingOnline

Brief title
POx study

Condition

- Metabolic and nutritional disorders congenital
- Renal disorders (excl nephropathies)

Synonym
Hyperoxaluria, Oxalosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: End stage renal disease, Hyperoxaluria, Plasma oxalate

Outcome measures

Primary outcome

Reference values for plasma oxalate levels in patients with ESRD.

Secondary outcome

Reference values for plasma glycolate levels in patients with ESRD.

Study description

Background summary

Oxalate is a metabolic end product of glyoxylate metabolism. It is produced by the liver and excreted in the urine. Once renal failure develops, patients are unable to excrete oxalate in the urine, which leads to a rise in plasma oxalate levels. Until now, normal values of plasma oxalate levels in patients with end-stage renal disease (ESRD) have not been established. The lack of reference values complicates the interpretation of the increased values found in ESRD patients. This is particularly relevant in patients with renal failure due to hyperoxularia, in whom elevated plasma oxalate levels can be ascribed both to the primary disease and the loss of kidney function. Primary Hyperoxaluria (PH) is a rare autosomal disease in which hepatic overproduction of oxalate (and glycolate) occurs. Secondary causes of hyperoxaluria include intestinal oxalate hyperabsorption and excessive dietary intake of oxalate. In both, the level of plasma oxalate influences therapeutic decision-making.

Study objective

The aim of this study is to establish reference values for plasma oxalate and plasma glycolate levels in patients with chronic kidney insufficiency. Values in patients with PH and secondary hyperoxaluria will be compared to values measured in patients on renal replacement therapy (RRT) in our centre and patients with pre-terminal renal insufficiency.

Study design

This is a cross-sectional, observational study. Plasma samples will be obtained from patients with pre-terminal renal insufficiency during regular outpatient

visits and from patients on renal replacement therapy (RRT) both prior to and after regular hemodialysis or peritoneal dialysis treatments.

Study burden and risks

There is no additional risk or burden associated with participation. Patients with pre-terminal renal insufficiency will undergo blood sampling for plasma oxalate and glycolate levels during regular outpatient clinic visits. Blood will be drawn prior to dialysis for patients on RRT.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

Patients with estimated glomerular filtration rate < 30 ml/min/1,73 m2 regardless the underlying cause of renal insufficiency.

Exclusion criteria

Patients who are unable to give informed consent.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-06-2020
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	12-03-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-06-2022
Application type:	Amendment

Review commission: METC Amsterdam UMC

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	NL72225.018.20