*Screening for Albuminuria at the first line for early identification of chronic kidney disease

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Primary objectives:To perform a study to:1. Estimate the prevalence of elevated albuminuria in subjects with a high risk of chronic kidney disease in the Netherlands.2. Evaluate which screening approach would be most effective based on costs per...

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

Summary

ID

NL-OMON54293

Source
ToetsingOnline

Brief title
SALINE

Condition

- Nephropathies

Synonym
chronic kidney disease

Research involving
Human

Sponsors and support

Primary sponsor: General Practitioners Research Institute
Source(s) of monetary or material Support: Astra Zeneca,Astra Zeneca Nederland

Intervention

Keyword: albuminuria, chronic kidney disease, hidden kidney disease, screening

Outcome measures

Primary outcome

1. Elevated albuminuria, defined as a urinary albumin creatinine ratio (UACR) >= 3.0 mg/mmol.

2. Average screening costs per subject that was identified as having elevated albuminuria. All costs considered are mentioned in chapter 8.1.1.

Secondary outcome

1. Unrecognized chronic kidney disease, defined as elevated albuminuria, not reported by the subject or previously recorded in electronic medical records of the subjects* general practice or pharmacy.

2. Persistent elevated albuminuria, defined as elevated albuminuria persisting despite good adherence (score 4 (=doses seldom missed) or 5 (= doses never missed) reported in MARS) to treatment with RAS-inhibitors for at least 6 weeks prior to elevated albuminuria assessment

3. Change in frequency of cardiovascular risk factor monitoring, defined as the difference between the frequency of cardiovascular risk factor monitoring in participants 3 years before and 6 months after targeted albuminuria screening.

4. Changes in cardiometabolic drug prescriptions, defined as changes in any prescription for cardiovascular disease or CKD 6 months after targeted albuminuria screening compared to three years before.

Study description

Background summary

Kidney disease, cardiovascular disease and Diabetes Mellitus are closely interrelated. Reducing modifiable cardiovascular risk factors has an effect on preventing both cardiovascular and renal damage. Early detection and appropriate treatment of kidney disease is important as this may prevent future cardiovascular complications and end-organ damage more effectively than intervention in more advanced stages of disease. There is a well-established relationship between albuminuria and renal- and cardiovascular disease. Elevated albuminuria has a relatively high prevalence in the general population (5-9%). The prevalence of albuminuria is even higher in patients with type 2 Diabetes Mellitus (20-40%) and in patients with hypertension (10-15%). Adequate treatment of albuminuria, preferable at early stages can prevent both cardiovascular and renal disease progression. However, scarce epidemiological data show that albuminuria measurements are only conducted in a minority of individuals and disease recognition is suboptimal, even in high-risk groups. This leaves a large proportion of patients not identified, and thus not adequately treated. The current study aims to evaluate if and how early identification of chronic kidney disease by targeted screening of albuminuria levels is feasible in primary care (pharmacies and general practitioners) to optimally discover and treat patients with elevated albuminuria.

Study objective

Primary objectives:
To perform a study to:
1. Estimate the prevalence of elevated albuminuria in subjects with a high risk of chronic kidney disease in the Netherlands.
2. Evaluate which screening approach would be most effective based on costs per identified patient with elevated albuminuria, via pharmacies or general practices.

Secondary objectives:
1. To estimate the prevalence of unrecognized chronic kidney disease in subjects with a high risk of chronic kidney disease.
2. To estimate the prevalence of persistent elevated albuminuria under adequate treatment with renin-angiotensin system (RAS) inhibitors in subjects with a high risk of chronic kidney disease.
3. To assess frequency of cardiovascular risk monitoring by general practitioners after targeted albuminuria screening.
4. To assess changes in cardio-metabolic drug prescriptions after targeted screening.

Study design

Cross-sectional study in Dutch pharmacies and general practices.

Study burden and risks

All selected subjects will be asked to participate on a free-will base and to send a signed informed consent form with a completed short questionnaire to GPRI. They will be asked to collect urine using the PeeSpot and to send this to a laboratory by postal mail for a measurement of albuminuria. Subjects will be informed about the results and, only in case of elevated albuminuria levels, the subject will be asked to repeat the procedure for a confirmational measurement. If the confirmational measurement is negative, a third measurement is needed. If recent (<11 months ago) albuminuria levels were available from the general practice and found to be elevated as well, a second confirmational PeeSpot measurement will not be needed. If recent albuminuria levels were not elevated, subjects will not be approached for this study.

When albuminuria is confirmed, treatment status will be reviewed and cardiovascular risk factors will be assessed during a visit. Length, weight, blood pressure, heart rate, point of care HbA1c and creatinine will be measured. Measurements performed during this visit are non-invasive and part of standard care in general practice and therefore not associated with additional risks. A benefit for the patient could be that elevated albuminuria may be detected earlier because of the screening, and thus comes with health benefits, such as adequate treatment of impaired renal function and medication monitoring by the pharmacy, which has been proven to be effective in preventing adverse events of medication.

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

Diabetes Mellitus (diagnosis or prescription for the disease based on the NHG guidelines)
Adipositas (diagnosis)
Hypertension (diagnosis or prescription for the disease based on the NHG guidelines)
Cardiovascular disease (diagnosis, specified in protocol section 4.2.2)
Lipid disorder (diagnosis or prescription for the disease based on the NHG guidelines)
Age 45-80 years

Exclusion criteria

Pregnancy
Inability to write or understand the informed consent form
Known normal (<3mg/mmol) albuminuria status within 18 months prior

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-11-2021
Enrollment:	112
Type:	Actual

Ethics review

Approved WMO Date:	12-10-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-01-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-01-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	NL78748.056.21