Screening for Chronic Kidney Disease among Older People across Europe (SCOPE)

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The specific objectives of the SCOPE project will be:O1. to assess existing methodologies for CKD screening among older adults using real-life data from a cohort of 75+ older patients; O2. to investigate novel and potentially useful application of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nephropathies
Study type	Observational invasive

Summary

ID

NL-OMON46292

Source
ToetsingOnline

Brief title
SCOPE

Condition

- Nephropathies

Synonym
Chronic Kidney Disease, End Stage Renal Disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: EU: Horizon 2020 Programme (grant agreement nr. 634869)

Intervention

Keyword: Chronic kidney failure, End stage renal disease, Older people

Outcome measures

Primary outcome

The primary study endpoints will be the rate of eGFR decline and the incidence of ESRD.

- Creatinine-based eGFR will be calculated using the Berlin Initiative Study 1 (BIS1) equation, which is the only method specifically developed in a population older than 70 years

- ESRD will be defined as GFR <15 mL/min/1.73 m2 or dialysis.

Secondary outcome

Secondary study endpoints include conventional and geriatric outcome measures, such as:

i. kidney function decline as estimated by novel application of existing biomarkers (cystatin C, beta2-microglobulin, beta-trace protein) or innovative biomarkers (proteomic/metabolomic) (see following sections for details).

ii. changes in biological and molecular markers linked to aging processes

iii. CKD complications (anemia, hyperphosphatemia, acidosis, hypoalbuminemia, hyperparathyroidism, hyperkaliemia);

iv. incidence of major comorbidities (information about CV events will include incident myocardial infarction, hospitalization for unstable angina, transient ischemic attack/stroke, heart failure events, interventional cardiology events, peripheral vascular intervention, and stent thrombosis);

v. overall and CV mortality (including death resulting from acute myocardial

infarction, sudden cardiac death, heart failure, stroke, CV procedures, CV

hemorrhage, and other CV causes);

vi. adverse drug reactions (ADRs);

vii. self-reported disability and objectively measured physical performance

decline; cognitive impairment; depression; malnutrition/undernutrition;

viii. health-related quality of life;

ix. healthcare resource consumption, including the estimation of caregiver

burden, and model based cost-effectiveness.

Study description

Background summary

The progressive aging of the population in industrialized countries is accompanied by an increase in the prevalence of chronic diseases, including CKD. Previous studies showed that age standardized rates of stage 3-5 CKD (i.e. at least moderate degree of kidney disease) was 6.1% among males and 13.1% among females in the adult population aged 55-64 years, while the corresponding figures in the population aged 75-84 years were 33.2% and 41.7%, respectively. Similarly, the prevalence of eGFR<60 ml/min/1.73m2 increased with age in both genders, from 1% among subjects aged 18*24 years to more than 30% among people aged 75 years or more. Thus, CKD has a relevant public health burden in the older population, resulting in an increased risk of ESRD, morbidity and mortality. Besides increasing the risk of ESRD, morbidity and mortality, CKD also affect outcomes relevant to older people. Indeed, reduced estimated glomerular filtration rate (eGFR) was found associated with lower scores in subjective physical function and physical activity scales. In the Cardiovascular Health Study cohort including 5,888 persons aged 65 or more the cross-sectional prevalence of a limitation in activities of daily living (ADL) was 12% among participants with CKD compared to 7% among participants without CKD. Additionally, low eGFR was associated with increased risk of worsening disability, defined as the loss of 1 or more ADLs over 6-year follow-up, among community-dwelling older individuals enrolled in the InChianti study. Finally, a recent systematic review showed that CKD was consistently associated with increasing frailty or reduced physical function. Additionally, frailty was associated with a greater than two-fold higher risk of dialysis and/or death in patients with CKD.

Cognitive impairment has been frequently observed in patients with CKD especially in older subjects. CKD is related to a wide range of deficits in cognitive functioning including verbal and visual memory and organization, and components of executive functioning and fluid intellect. Small vessel disease, which is known to contribute to the pathophysiology of CKD, can lead to cerebral ischemic lesions, both in the form of silent or subclinical cerebral infarcts or white matter lesions, increasing the risk of cognitive decline and dementia.
Depression is frequently observed in older patients with CKD.This is of great importance because the presence of depression in CKD is associated with poorer outcomes such as hospitalizations, progression to dialysis, and increased morbidity and mortality. About 20%-30% of patients with CKD have clinical depression. In addition to its negative impact on cognition and mood, CKD may also affect sensory function. Indeed, CKD is considered a relevant risk factor for retinal abnormalities which may threaten vision, thus worsening quality of life and causing dependency.
Nutrition is also a major problem for CKD patients; a decline in kidney function is usually followed by a spontaneous decrease in energy and protein intake as well as in anthropometric measures, which in turn may favor the onset of frailty and disability in older patients. Sarcopenia, defined as a loss of muscle mass with limited mobility/low muscle function (gait speed and hand grip strength) is a common finding in older adults and its prevalence rises sharply with declining kidney function. Cachexia is an important cause of death in older CKD patients.
Finally, CKD increases the risk of adverse drug reactions (ADRs). When renal function declines, many drugs or their active metabolites that depend on renal excretion may accumulate. For this reason, patients with CKD may be more vulnerable to a given drug effect and may be potentially exposed to an increased risk of toxicity. For this reason, early detection of CKD also represents a major step towards reducing risk of ADRs and increasing safety in older complex patients with multimorbidity and polypharmacy.

(protocol C1. for references)

Study objective

The specific objectives of the SCOPE project will be:
O1. to assess existing methodologies for CKD screening among older adults using real-life data from a cohort of 75+ older patients;
O2. to investigate novel and potentially useful application of existing and innovative biomarkers of CKD in older people;
O3. to evaluate the cost-effectiveness of existing and innovative CKD screening strategies in a population at high risk of developing kidney function decline and ESRD (including the novel application of existing biomarkers, the use of innovative ones, and CGA tools);
O4. to provide evidence for further development of European recommendations and

guidelines, as well as an European education programme in this field.

Study design

The SCOPE study will be an observational, multinational, multicenter, prospective cohort study targeting CKD screening in community-dwelling subjects aged 75 years or more. Participants will undergo clinical and laboratory evaluations at the baseline (enrollment), and will be followed up at 12 and 24 months. An intermediate telephone follow-up will be carried out at 6 and 18 months. The study design complies with the Declaration of Helsinki and Good Clinical Practice Guidelines.

Study burden and risks

Participation in a clinical study involves a very close scrutiny of health condition. In general, the results of this study may help to reduce the risk of end stage renal disease, disability and mortality among older people. Blood samples can cause mild discomfort such as dizziness, pain, redness or a small bruise at the puncture site. Rarely this can cause an infection. The potential risks and impact for the participants are minimal so the benefits outweigh the potential small disadvantages.

Three hospital visits at baseline, after 12 months and after 24 months, approximately 1 hour per visit.
The visits are planned as close as possible to the regular visits. The following activities will be performed:
- Questionnaires: demographics, medical history and medication use, minimal mental state examination (MMSE), Geriatric depression scale (GDS), Activity of Daily Living (ADL), Instrumental activities of daily living (IADL), Mini nutritional assessment (MNA), 24-h dietary recall, history of falls, socioeconomic status, Quality of Live (Euro-Qol 5D), zarit burden interview, events (adverse drug reaction, new diagnosis at 12-24 months)
- Physical assessment: height, weight, waist/hip circumference, bloodpressure and functional vascular properties with Mobil-o-graph ® (Mobil-o-graph only in the Netherlands = a non-invasive measurement using upper arm cuff), physical examination, short physical performance battery, bioelectrical impedance analysis, hand grip strength
- Blood/urine samples, sampling will be performed after fasting for 12 hours (preferably)

2 phone based follow up (6 and 18 months)
Questionnaires: Activity of Daily Living (ADL), Instrumental activities of daily living (IADL), healthcare resource consumption, events (adverse drug reaction, new diagnosis)

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 patients and their spouses aged 75 and over, attending the outpatient services at participating institutions.

Exclusion criteria

Only patients with ESRD or dialysis, history of solid organ or bone marrow transplantation, active malignancy within 24 months prior to screening or metastatic cancer, life expectancy less than 6 months, severe cognitive impairment (MMSE<10), any medical or other reason (e.g. known or suspected inability of the subject to comply with the protocol procedure) that investigator opinion that the subject is unsuitable for the study, and patients unwilling to provide consent and those who cannot be followed-up will be excluded from the study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-08-2016
Enrollment:	350
Type:	Actual

Ethics review

Approved WMO Date:	07-03-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-05-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-06-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-06-2017
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL56039.078.15