Rapid detection of chronic polyneuropathy in patients with diabetes mellitus or chronic kidney failure

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We aim to investigate if the E-PSS is able to discriminate patients with polyneuropathy from patients without polyneuropathy in patients with diabetes and/or chronic kidney failure and determine an optimal cut-off value. Primary Objective: Is the...

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

Summary

ID

NL-OMON56883

Source
ToetsingOnline

Brief title
DE SNAP study

Condition

- Peripheral neuropathies

Synonym
(peripheral) neuropathy, nerve disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Prinses Beatrix Spierfonds

Intervention

Keyword: Chronic kidney failure, Chronic polyneuropathy, Detection, Diabetes Melltius

Outcome measures

Primary outcome

The main study parameter is the performance of the E-PSS expressed as area under the curve (AUC) and visualize this with a receiver operating characteristic (ROC) curve. Using the Youden*s J statistic we will determine the cut-off value with the best discrimination performance. We will evaluate the performance further with the sensitivity and specificity for this cut-off value.

Secondary outcome

Secondary objectives are:

- the prevalence of polyneuropathy,

- the proportion of underdiagnosed polyneuropathy

- the prevalence of co-occurrence of risk factors

- usage of neuropathic painkillers

- the relationship between presence of polyneuropathy and severity, duration and treatment of the underlying disease

Study description

Background summary

Polyneuropathy is often undiagnosed. It has considerable morbidity and is a substantial burden to the health care. It is a multifactorial disease with diabetes and kidney failure as prominent known risk factors. Early detection is important, but diagnosing polyneuropathy is complex. The Erasmus Polyneuropathy

Symptom Score (E-PSS) is a newly developed simple six-item symptom score. It has only been validated in a neurological outpatient clinic, but not yet in an internal medicine outpatient setting with patients with diabetes mellitus and kidney failure.

Study objective

We aim to investigate if the E-PSS is able to discriminate patients with polyneuropathy from patients without polyneuropathy in patients with diabetes and/or chronic kidney failure and determine an optimal cut-off value.

Primary Objective:
Is the Erasmus Polyneuropathy Symptom Score (E-PSS) questionnaire able to discriminate patients with polyneuropathy from patients without polyneuropathy in patients with diabetes mellitus and/or chronic kidney failure and what is the optimal cut-off value?

Secondary Objective(s):
- What is the prevalence of polyneuropathy in patients with diabetes mellitus and/or chronic kidney failure at a non-academic internal medicine outpatient clinic?
- How often is polyneuropathy underdiagnosed in patients with diabetes mellitus and/or chronic kidney failure at a non-academic internal medicine outpatient clinic?
- Is the presence of polyneuropathy related to the severity/regulation, duration, and treatment of the underlying condition?
- What is the prevalence of co-occurrence of risk factors of polyneuropathy at a non-academic internal medicine outpatient clinic?
- How often are neuropathic painkillers used in patients with diabetes mellitus and/or chronic kidney failure at a non-academic internal medicine outpatient clinic?

Study design

We will perform a cross-sectional observational study.

Study burden and risks

During a visit of 30-40 min at the Albert Schweitzer hospital participant will fill in the E-PSS questionnaire, undergo a brief history taking, as well as a neurological examination and nerve conduction study (NCS). The NCS can be slightly uncomfortable, but generally does not cause any pain, and is not harmful to muscles or nerves. The risk for the participants is negligible. The benefit for the individual participant is small, but if a polyneuropathy is detected this can be treated following the current guidelines, whereas this otherwise would be undiagnosed. The most important benefit will be on a group

level to improve knowledge regarding the occurrence and diagnosis of polyneuropathy in patients with diabetes mellitus and/or chronic kidney failure. The E-PSS is a simple and quick diagnostic tool that aims to detect polyneuropathy and could lead to prevent under diagnosis of polyneuropathy in patient with diabetes mellitus and/or chronic kidney failure.

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 year and diagnosed with diagnosed with diabetes mellitus type 2 or type 1 for more than 10 year (fasting glucose >= 7.0 mmol/l or non-fasting glucose >= 11.0 mmol/l or use of any antidiabetics) and/or chronic kidney failure (eGFR < 30 ml/min/1.73m2)

Exclusion criteria

unable to fill in the symptom questionnaire (e.g. a language barrier or severe cognitive problems)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-08-2024
Enrollment:	370
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	12-07-2024
Application type:	First submission
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	NL84325.078.24