# Adapted modified Toronto Clinical Neuropathy Score validated by quantitative sensory testing and nerve conduction studies for renal transplant recipients

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Primary objective:To validate the adapted modified Toronto Clinical Neuropathy Score (amTCNS) with quantitative sensory testing and nerve conduction studies. Hypothesis: a. Quantitative sensory testing is correlated to the amTCNS indicating that...

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Peripheral neuropathies |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON54903

**Source**
ToetsingOnline

**Brief title**
Validation of adapted modified Toronto Clinical Neuropathy Score

### Condition

- Peripheral neuropathies

**Synonym**
peripheral nervous system disease, polyneuropathy

**Research involving**
Human

## Sponsors and support

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

## Intervention

**Keyword:** 'adapted modified Toronto Clinical Neuropathy Score', diagnostics of polyneuropathy, polyneuropathy in renal transplant recipients, sensory polyneuropathy

## Outcome measures

### Primary outcome

The main study endpoint is to validate the amTCNS result with quantitative

sensory testing and nerve conduction studies.

The following endpoints will be included:

1. amTCNS result (score between 0 and 30)

2. Quantitative sensory testing: thermal threshold testing

3. Nerve conduction studies: SNAP amplitude, CMAP amplitude and distal motor

latency, nerve conduction velocity, H-reflex

### Secondary outcome

In addition to the amTCNS, temperature sense, muscle strength and reflexes will

be examined to assess whether they should be included in the amTCNS for a

better specificity and sensitivity of the score for quantifying the severity of

polyneuropathy.

# Study description

### Background summary

Sensory polyneuropathy (PNP) is one of the most prevalent neurological disorders and a common finding in renal transplant recipients (RTR). The aim is

to diagnose PNP with a questionnaire and simple physical exam. The adapted modified Toronto Clinical Neuropathy Score (amTCNS) is such a score method. However, the amTCNS first needs to be validated with the golden standard for diagnosing PNP (Quantitative Sensory Testing (QST) and Nerve Conduction Testing (NCS)). In addition to the benefit of better mapping the incidence of PNP, early diagnosis and treatment of certain PNP may prevent further worsening of symptoms. The medication in question can also be adjusted.

## Study objective

Primary objective:
To validate the adapted modified Toronto Clinical Neuropathy Score (amTCNS) with quantitative sensory testing and nerve conduction studies.
Hypothesis:
a. Quantitative sensory testing is correlated to the amTCNS indicating that small nerve fibre deficits can be detected.
b. Nerve conduction studies are correlated to the amTCNS indicating that large nerve fibre deficits can be detected.

Secondary objective:
To define reference values of the amTCNS dependent on predictors in a healthy subject population.

## Study design

This research protocol contains a cross-sectional study or can alternatively be described as a validation study. The aim is to investigate the reliability of the amTCNS. This is a clinical score designed to capture symptoms and signs of sensory PNP. The amTCNS will be validated with quantitative sensory testing and nerve conduction studies which are considered as golden standard for diagnosing small fibre neuropathies and large fibre neuropathies, respectively.
The aim is to validate the amTCNS for a population of RTR in order to reliably diagnose PNP.

## Study burden and risks

Participants of this study will attend the research facilities for a single study visit of 150 minutes. During this study quantitative sensory testing and nerve conduction studies will be performed. These examinations can cause some discomfort during the test, but side effects very rarely occur. Both are tests that are performed in daily clinical practice in the regular patient care.

# 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 >=18 years of age
Patient is able to understand the Dutch language and capable to intellectually comprehend questionnaires and physical tests
Signed and dated informed consent prior to any study-related procedures
Previous participation in the TransplantLines cohort study and biobank

## Exclusion criteria

Patient refusal
Amputation of lower or upper limb(s) bilaterally, trauma of limbs
Patients with a pacemaker or ICD

Use of mind-altering drugs in previous 24 hours
Metal osteosynthesis after bone fracture (in arms or legs)
Patients with mononeuropathies in examined nerves

# Study design

## Design

**Study type:** Observational non invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 20-12-2021 |
| Enrollment: | 205 |
| Type: | Actual |

# Ethics review

Approved WMO

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|---|---|
| Date: | 23-03-2021 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

# 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 |
|---|---|
| ClinicalTrials.gov | NCT04664426 |
| CCMO | NL74617.042.20 |