

# The aetiology of nocturnal symptoms in carpal tunnel syndrome

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Primary Objective: To study whether nocturnal symptoms of CTS depend on wrist position and, if so, on which position. Identifying which wrist position aggravates CTS could help design a more effective splint. Secondary Objective: To study whether...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Peripheral neuropathies
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON42718

### Source

ToetsingOnline

### Brief title

Nocturnal symptoms in carpal tunnel syndrome

### Condition

- Peripheral neuropathies

### Synonym

carpal tunnel syndrome, compression neuropathy of the median nerve, nerve entrapment in the wrist

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Neurologie

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** carpal tunnel syndrome, nocturnal pain, paraesthesiae, pathophysiology

## Outcome measures

### Primary outcome

Hypothesis 1: There is a specific position of the wrist causing nocturnal symptoms. 1a.) This position is the same in all patients. Parameter: The average angle of the wrist 15 minutes before every awakening compared to the average angle of the wrist during 15 minutes at the same time in another night in which the patient did not awake at that time.

Hypothesis 2: Nocturnal symptoms of CTS are related to a prolonged position of the wrist. Parameter: variance in position of the wrist during the 60 minutes prior to awakening compared with to variance in position during the same 60 minutes in another night in which the patient did not awake at that time.

### Secondary outcome

Hypothesis 3: Nocturnal symptoms of CTS are related to nocturnal drop in systemic BP. Parameter: BP preceding nocturnal symptoms compared to BP on a random chosen moment in that night in which the patient did not awake.

Hypothesis 4: Splinting of the wrist in neutral position results in a decrease of the frequency of nocturnal symptoms of CTS of at least 50%. Parameter: average frequency of awakenings during the first week compared to the second

week.

## Study description

### Background summary

Approximately 80% of patients with a compression of the median nerve in the carpal tunnel (carpal tunnel syndrome, CTS) report nocturnal awakening due to numbness or tingling of the hand. Patients typically move the wrist repetitively upon awakening to alleviate their symptoms. The presumed reason for this nocturnal aggravation is that the median nerve is subject to more compression than in daytime and becomes ischaemic which results in paraesthesia. There is no clear pathophysiological concept of why the nerve should become more ischaemic during sleep. We envisage the following possibilities:

- prolonged flexion of the wrist
- prolonged extension of the wrist
- drop in systemic blood pressure (BP) causing decrease in perfusion of the vasa nervorum of the median nerve.

Circumstantial evidence in favour of either prolonged flexion or extension of the wrist is found not only in the beneficial effect of movement after awakening, but also in the fact that nocturnal splinting of the hand can work. However, the evidence for effect of this conservative treatment is limited and the angle in which the wrist should be immobilised is unknown. No one has yet studied whether there is a correlation between the position of the wrist and subsequent awakening due to symptoms of CTS.

### Study objective

Primary Objective: To study whether nocturnal symptoms of CTS depend on wrist position and, if so, on which position.

Identifying which wrist position aggravates CTS could help design a more effective splint.

Secondary Objective: To study whether nocturnal symptoms of CTS depend on decrease in systemic BP.

### Study design

Observational mono-center study with an exploratory character.

The expected duration is five months.

## Study burden and risks

In addition to standard care, patients will fill in a short questionnaire regarding the severity of their complaints (Boston Carpal Tunnel Questionnaire, BCTQ ± ten minutes). They will sleep with the LWG during seven nights and with the ABPM at the contralateral arm during one night. Hereafter they will sleep seven nights with a splint (standard care) combined with a registration button and again fill in the BCTQ. The devices will be returned by the patient or picked up by the investigator, depending on the patient's preference. Sleeping with the LWG is unlikely to influence wrist position, although this cannot be formally tested. Sleeping with the ABPM can slightly reduce the quality of sleep because patients may occasionally wake up during the measurement. There are no risks associated with participation.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

- Electrophysiologically proven CTS
- History of nocturnal complaints of CTS leading to awakening  $\geq$  two times per night
- Age  $\geq$  18 years
- Ability to provide informed consent

## Exclusion criteria

- Working night shifts during the study period
- Any skin condition of the hand that would make wearing of the Leiden Wrist Goniometer (LWG) uncomfortable.
- The need for immediate surgery or other treatment for CTS
- Any reason patients can not wear an ABPM on the contralateral arm, such as previous brachial lymphadenectomy

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Basic science

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2015
Enrollment:	30
Type:	Anticipated

### Medical products/devices used

Generic name:	Splinting of the wrist at night (Carpal Tunnel polsbandage 454)
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Registration: Yes - CE intended use

## Ethics review

Approved WMO

Date: 01-09-2015

Application type: First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

## 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	NL53671.058.15