

# Sensation of the face in patients with unilateral facial nerve palsy

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Cranial nerve disorders (excl neoplasms)
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON53450

### Source

ToetsingOnline

### Brief title

Facial sensation in facial nerve palsy

### Condition

- Cranial nerve disorders (excl neoplasms)

### Synonym

facial nerve palsy, facial paralysis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Medisch Universitair Ziekenhuis Maastricht

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

## Intervention

**Keyword:** Facial nerve, Facial palsy, Quality of life, Sensation

## Outcome measures

### Primary outcome

- To evaluate sensation of the face in patients with unilateral facial nerve palsy and compare the sensation of the affected side to the non-affected side.
- To compare sensation of the face in patients with synkinesis after facial nerve palsy to patients with hemifacial spasms due to a neurovascular conflict.

### Secondary outcome

- To evaluate the change in sensation of the face at the beginning and during recovery of facial nerve palsy.
- To measure quality of life by use of the FACE-Q Paralysis scale in patients with unilateral facial nerve palsy.
- To investigate whether a correlation exists between sensation of the face and course of the facial palsy in time.

## Study description

### Background summary

Facial nerve palsy is a peripheral nerve dysfunction causing ipsilateral facial muscle weakness or even (temporary) loss of function. Some patients have described changes in facial sensation during and after their facial palsy, ranging from hyperesthesia and numbness, to altered temperature sensation or even pain. Few studies have evaluated facial sensation during facial palsy and the existing studies are cross-sectional and have measured only static pressure/touch and two-point discrimination, without assessing moving touch and hot/cold temperature. Besides influencing sensation, a facial nerve palsy can have a significant impact on patient's mood and quality of life (QoL).

## Study objective

The primary objective of our study is to evaluate sensation (static/moving pressure/touch, hot/cold temperature and pain threshold) of the face in patients with unilateral facial nerve palsy and compare the sensation of the affected side to the non-affected side. Besides, we want to compare sensation of the face between patients with synkinesis after facial palsy and patients with hemifacial spasms due to a neurovascular conflict

The secondary objectives of our study are to evaluate the change in sensation of the face at the beginning and during recovery of facial nerve palsy, to measure QoL by use of the newly developed Paralysis module of the FACE-Q, and to investigate a possible correlation between the course of the facial palsy en sensation of the face. Eventually, we would like to further investigate the relationship between the (largely) motor facial nerve and the (largely) sensible trigeminal nerve. The connection and relationship between the two cranial nerves might play an important role in the development of synkinesis and is therefore important to evaluate and gain more knowledge on.

## Study design

A prospective cohort study conducted in the Maastricht University Medical Centre (MUMC+).

## Study burden and risks

Participation is voluntarily. Participants can withdraw at any time during the study without further consequences. There are no direct risks associated with participation, as the measurements for the study are non-invasive, harmless, and not painful. Patients may experience extra follow-up visits as beneficial and results collected during the study could potentially increase insight in the pathophysiology of facial nerve paralysis.

## Contacts

### Public

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NL

### 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**

Group 1 (new onset facial palsy patients):

- 18 years or older, and;
- (A history of) unilateral facial nerve palsy, independent of etiology

Group 2A/B (facial synkinesis/hemifacial spasms patients):

- 18 years or older, and;
- (A history of) unilateral facial nerve palsy, independent of etiology, and;
- $\geq 1$  year after the start of the facial nerve palsy, or;
- Hemifacial spasms caused by a neurovascular conflict

### **Exclusion criteria**

Group 1:

- First presentation longer than 3 weeks after onset of facial nerve palsy (relative exclusion criterium, this is not the case for patients with synkinesis)
- Bilateral facial nerve palsy

Group 2A/B:

- (A history of) bilateral facial nerve palsy

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 07-11-2023

Enrollment: 63

Type: Actual

## Ethics review

Approved WMO

Date: 18-01-2023

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

## 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

CCMO

### ID

NL82725.068.22