# COVORTS study: the COVid cohORT on Smell loss

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To investigate the natural course of smell alterations in relation to COVID-19. To investigate differences in neuroanatomical structures (olfactory bulb) and neural activity between patients with anosmia and parosmia

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Appetite and general nutritional disorders |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON54465

**Source**
ToetsingOnline

**Brief title**
COVORTS

### Condition

- Appetite and general nutritional disorders
- Respiratory tract infections

**Synonym**
corona, smell and taste disorders

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Wageningen Universiteit
**Source(s) of monetary or material Support:** ZonMW

## Intervention

**Keyword:** COVID-19, parosmia, smell, taste

## Outcome measures

### Primary outcome

Objective assessment of parosmia by means of the SSParoT;

Objective olfactory function by means of Sniffin*Sticks;

Objective gustatory function by means of Taste Strips.

With this, we will assess longterm prevalence of parosmia within the cohort, as well as describe the smell and taste ability of patients. Mean and median time interval to clinical improvement (recovery) will be reported as measure of duration of parosmia.

For the neuroimaging part: differences in olfactory bulb volume, differences in volume of olfactory-related brain regions, and differences in activation of brain regions upon odor stimuli between patients with smell loss (i.e. anosmia and hyposmia) and parosmia will be analyzed.

### Secondary outcome

To assess the longterm prevalence of anosmia, hyposmia, and taste loss.

To measure smell and taste function subjectively longitudinally in a cohort of Covid-19 patients with self-reported smell loss.

To assess the impact of smell/taste changes on eating behavior and quality of life.

To assess changes over time in olfactory bulb volume, volume of

olfactory-related brain regions over time, and functional responses in a subset

of Covid-19 patients

# Study description

### Background summary

Smell loss is one of the most frequent symptoms -and predictor- of COVID-19, can be long-lasting and have devastating impact on eating behavior and daily life. In particular, patients often report that after a period of smell loss (anosmia), they develop a distorted sense of smell (parosmia). Yet the course and frequency of this conversion is unknown, and treatment or advice and prognosis is currently still lacking.

### Study objective

To investigate the natural course of smell alterations in relation to COVID-19. To investigate differences in neuroanatomical structures (olfactory bulb) and neural activity between patients with anosmia and parosmia

### Study design

A prospective cohort study to assess smell alterations in COVID-19 patients. Every 3 months, patients will be objectively tested on their smell and taste ability, including parosmia. In addition, patients will fill out online questionnaires related to their smell and taste ability, trigeminal sensations, eating behavior, quality of life, and perform an at-home test every month. A subset of patients will be included in an observational case-control study with one time follow-up, where we will perform neuroimaging. Those patients will participate in one or two scanning sessions (upon inclusion, and potential followup after 6 months), including structural and functional MRI in which patients are exposed to different olfactory stimuli.

### Study burden and risks

The study involves a maximum of 20 test sessions. For 13 test sessions (T0-T12), patients can perform tests and questionnaires independently at their own homes (60min). For 5 test sessions (T0, T3, T6, T9, T12), a researcher will additionally visit the patients at their own home to perform objective smell and taste testing (max 2 hrs). For the 2 scanning sessions, patients will need to come to the hospital (1hr). There is no therapeutic benefit for the patients by participating in this study. There are no known risks associated with the used odors, tastants, and tests. MRI is an eminently safe technique; there are

no risks that have been associated with the acquisition of MRI data per se. The only burden is the time-investment for the patient.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

patients (18-60 years) with persistent (> 1month) self-reported smell loss within three months after COVID-diagnosis.

For the neuroimaging substudy: patients (18-60 years) with persistent (> 1month) self-reported smell loss after COVID-diagnosis.

### Exclusion criteria

any pre-existing olfactory or gustatory disorders ( i.e. more than 2 weeks prior to the covid-infection)

for the neuroimaging subpart:
pregnant, or intending to become pregnant during the course of the study
Having a contra-indication to MRI scanning

## Study design

### Design

**Study type:** Observational invasive

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

### Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 02-11-2021 |
| Enrollment: | 75 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 28-09-2021 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 20-01-2022 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO | |

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| Date: | 08-07-2022 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 14-11-2023 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

ID: 28538
Source: Nationaal Trial Register
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL77954.091.21 |
| OMON | NL-OMON28538 |