

COVORTS study: the COVid cohORT on Smell loss

Published: 28-09-2021

Last updated: 19-03-2025

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

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

Public

Wageningen Universiteit

Stippeneng 4
Wageningen 6708 WE
NL

Scientific

Wageningen Universiteit

Stippeneng 4
Wageningen 6708 WE
NL

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

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 02-11-2021

Enrollment: 75

Type: Actual

Ethics review

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

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: NTR
Title:

In other registers

Register	ID
CCMO	NL77954.091.21
OMON	NL-OMON28538