The COVid cohORT on Smell loss

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28538

Source
Nationaal Trial Register

Brief title
COVORTS

Health condition

COVID-19

Sponsors and support

Primary sponsor: WUR
Source(s) of monetary or material Support: ZonMW

Intervention

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. For the neuroimaging part: activation of brain regions in response to odor administration; activation of functional connectivity networks in the brain in response to odor administration; volume of the olfactory bulbs; total brain volume and volume of olfactory-related brain regions

Secondary outcome

Self-reported smell, taste, parosmia and trigeminal sensations; scores on home-use-test (https://riech-check.de/); eating behavior, as measured by the Appetite, Hunger and Sensory Perception questionnaire and VAS ratings on food enjoyment and appetite; quality of life, as measured by the Questionnaire of Olfactory Disorders

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. Therefore, we will investigate both the natural course of smell alterations in relation to Covid-19 and differences in neural activity between anosmia and parosmia. This will be done in a prospective cohort study. A subset of patients will be included in an observational case-control study with one time follow-up, where we will perform neuroimaging. 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. For the neuroimaging part, patients will participate in two scanning sessions (upon inclusion, and follow-up after 6 months), including structural and functional MRI in which patients are exposed to different olfactory stimuli.

Study objective

We expect that smell and taste function will be decreased shortly after infection, but that smell and taste function will recover over time. Part of the patients will develop parosmia. Smell loss due to a Covid-19 infection will affect structure and function of olfaction-related areas in the brain.

Study design

The study involves a maximum of 20 test sessions (T0 – T12, plus the additional objective tests at T0, T3, T6, T9 and T12, plus 2 neuroimaging sessions). Test sessions will take place each month.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

Aged between 18-60 years, as olfactory function typically declines after the age of 60 years; recent Covid-19 infection (< 3 months), confirmed with a positive PCR-test, performed at a hospital or by the GGD; persistent self-reported smell loss (> 1 month); willing to comply with the study procedures; Dutch speaking; having given informed consent

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2021
Enrollment:	75
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
For the sharing of data, the ZonMW guidelines in regard to FAIR data management will be applied.

Ethics review

Positive opinion

Date:	07-10-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54465
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9780
CCMO	NL77954.091.21
OMON	NL-OMON54465

Study results