The COVid cohORT on Smell loss

Gepubliceerd: 07-10-2021 Laatst bijgewerkt: 19-03-2025

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28538

Bron
NTR

Verkorte titel
COVORTS

Aandoening

COVID-19

Ondersteuning

Primaire sponsor: WUR
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd

Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2021
Aantal proefpersonen:	75
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

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

Ethische beoordeling

Positief advies

Datum:	07-10-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54465
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9780

Register	ID
CCMO	NL77954.091.21
OMON	NL-OMON54465

Resultaten