# COrticosteroids for COVID-19 induced loss of Smell - COCOS trial (AMENDMENT)

Published: 12-10-2021
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To determine the efficacy of a short high-dose treatment of oral prednisolone for persistent loss of smell after COVID-19 infection in the long term (>12 weeks). ADD: determining the clinical course/natural recovery of loss of smell and taste...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON54199

**Source**
ToetsingOnline

**Brief title**
COCOS trial

### Condition

- Other condition
- Ancillary infectious topics

**Synonym**
Anosmia, Smell disorder

**Health condition**

reuk

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** ZonMw;het COVID-19 program

## Intervention

**Keyword:** Corticosteroids, COVID-19, Smell

## Outcome measures

### Primary outcome

Primary outcome is objective olfactory function by means of Sniffin* Sticks.

### Secondary outcome

Secondary endpoints are objective gustatory function by means of Taste Strips.

In addition patients will fill in questionnaires related to their smell and

taste ability, trigeminal sensations, quality of life and nasal symptoms.

# Study description

### Background summary

Loss of smell (anosmia) is common in COVID-19 infections. Most patients regain normal smell within 4 weeks, but in 6-8% the smell does not fully recovery. These persistent smell disorders greatly influence daily life. It is thought that COVID-19 causes disorders in smell due to inflammation around the olfactory nerve and in olfactory pathways. Corticosteroids could reduce this local inflammatory response and improve smell.

Besides we want to obtain insight in the clinical course of loss of smell and taste after COVID-19 in the longer term (1 year after COVID-19) in order to better inform patients.

### Study objective

To determine the efficacy of a short high-dose treatment of oral prednisolone for persistent loss of smell after COVID-19 infection in the long term (>12 weeks).

ADD: determining the clinical course/natural recovery of loss of smell and taste after COVID-19 in the longer term (approx. 1 year after infection).

### Study design

Prospective, single centered, double blinded, placebo-controlled trial

ADD: cohort study that will last about a year

### Intervention

none

### Study burden and risks

Treatment with prednisolone can have side-effects. There is wide experience with this particular dosing regimen, which is generally well tolerated by patients. Main side effects include gastric problems, loss of sleep, mood swings, muscle cramps. Side effects stop after cessation of the treatment. . Potential benefit is improvement in smell and decrease of life-long disability. We believe the potential benefits is in proportion with the potential risks.

## Contacts

**Public**
Academisch Medisch Centrum

Heidelberglaan 100
Utrecht 3514XW
NL
**Scientific**
Academisch Medisch Centrum

Heidelberglaan 100
Utrecht 3514XW
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

### Inclusion criteria

- Infected with COVID-19, confirmed with a positive test (PCR or antigen by GGD)
- Persistent loss of smell after for longer than 12 weeks, (only for the patients who will yet be treated with prednisolon TDI < 30.5 on Sniffin* Stick test during second visit COCOS-trial )
- Age 18 years or older, capable of giving informed consent
• Good understanding of the Dutch language
• Treated with prednisolon in COCOS-trial
• Treated with placebo in COCOS-trial

### Exclusion criteria

• Pre-existing olfactory disorders.
• Chronic rhinitis or rhinosinusitis (with or without nasal polyps).
• Corticosteroids use (nasal, oral or intravenously) since positive COVID test..
• Pregnancy.
• Contra-indications of steroid use. which contains the following:
-Diabetes Mellitus for which drugs (subcutaneously or orally) are used
-Stomach ulcers/stomachbleeding
-Psychoses
-Active oncology for which treatment is indicated

## Study design

### Design

| | |
|---|---|
| Study phase: | 4 |
| Study type: | Interventional |

| | |
|---|---|
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Treatment

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Completed |
| Start date (anticipated): | 16-11-2021 |
| Enrollment: | 116 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Prednisolone |
| Generic name: | prednisolone |
| Registration: | Yes - NL intended use |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 12-10-2021 |
| Application type: | First submission |
| Review commission: | METC NedMec |
| Approved WMO Date: | 13-10-2021 |
| Application type: | First submission |
| Review commission: | METC NedMec |
| Approved WMO Date: | 14-07-2022 |
| Application type: | Amendment |
| Review commission: | METC NedMec |

# 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 | ID |
|---|---|
| EudraCT | EUCTR2021-004021-71-NL |
| CCMO | NL78693.041.21 |

# Study results

| | |
|---|---|
| Date completed: | 02-12-2022 |
| Results posted: | 13-12-2022 |
| Actual enrolment: | 111 |

**Summary results**
Trial ended prematurely

**URL result**
URL
Type
ext
Naam
bmcmedicine.biomedcentral.com
URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL

**Internal documents**
File