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

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