A phase 1b, randomized, double-blinded, placebo-controlled study of hydroxychloroquine in outpatient adults with COVID-19

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON49040

Source
ToetsingOnline

Brief title
EFC16855

Condition

- Viral infectious disorders

Synonym
Corona, COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: Sanofi-aventis

Source(s) of monetary or material Support: Sanofi

Intervention

Keyword: Corona virus, Covid-19, hydroxychloroquine, SAR321068

Outcome measures

Primary outcome

Primary endpoint:

- Change from baseline in nasopharyngeal SARS-CoV-2 viral load on Day 3 (if quantitative PCR is available)

- Number of participants by PCR result status (positive or negative) (if quantitative PCR is not available)

Secondary outcome

Secondary endpoints:

- Change from baseline to Day 5 in nasopharyngeal SARS-CoV-2 viral load

- Number of participants by PCR result status (positive or negative)

- Number of participants with COVID-19 symptoms by severity

- Time to resolution of COVID-19 symptoms

- Time to resolution of fever

- Percentage of participants with resolution of fever

- Percentage of participants hospitalized

- Number of participants with adverse events

Study description

Background summary

Hydroxychloroquine is a drug used for malaria and also for the treatment of certain types of rheumatism, among others rheumatoid arthritis and lupus. We do not know exactly how the drug works, however it is believed that it partially works by influencing the acidity in some parts of the cells in our body.
Several studies showed that this drug can decrease the inflammation by acting on the immune system. In a recent smaller study it showed that the treatment with hydroxychloroquine could decrease the amount of SARS-CoV-2 virus in the nose and throat. With this study we hope to answer this question.

Study objective

This study is designed to assess the antiviral activity of hydroxychloroquine in patients with SARS-CoV-2 virus. To evaluate the antiviral effects of hydroxychloroquine at the earliest stages of disease, the study will be conducted in outpatient adults immediately follow diagnosis of infection with SARS-CoV-2 virus.

Study design

Phase 1b, randomized, double-blinded, placebo-controlled study.

Intervention

- Hydroxychloroquine 200 mg or
- Placebo

Day 1: 4 capsules hydroxychloroquine or placebo, then 2 units hydroxychloroquine or placebo 6-8 hours later
Days 2-10: 1 capsule hydroxychloroquine or placebo 3 times daily

Study burden and risks

Burden and risks are related to the blood sampling, nasopharyngeale swab, and possible side effects of the study medication.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Participants * 18 years and * 80 years of age
- Participants with a diagnosis of COVID-19 via an approved or authorized molecular test
- Presence of symptoms compatible with COVID-19 at the time of screening
- Time between onset of symptoms and first dose of hydroxychloroquine or placebo is 96 hours or less
- Female participants must use an acceptable birth control method, as specified by each site and country

Exclusion criteria

- COVID-19 disease requiring the use of suplemental oxygen
- Electrocardiogram (ECG) tracing with QTc interval > 450 ms for men, > 470 ms for women (Fridericia algorithm recommended)
- Bradycardia (< 50 beats/min)
- History of cardiac disease (e.g. congestive heart failure, myocardial infarction)
- History of Glucose-6-phosphate dehydrogenase (G6PD) deficiency
- Women who are pregnant or breastfeeding
- Concurrent antimicrobial therapy
- Hydroxychloroquine use within 2 months before enrollment

- Known hypersensitivity to hydroxychloroquine or other 4-aminoquinoline compounds
- History of severe skin reactions such as Sevens-Johnson syndrome and toxic epidermal
necrolysis
- History of retinopathy
- Concurrent use of antiepileptic medications
- History of arrythmia, concurrent use of anti-arrhythmic drugs, or family history of sudden
cardiac death
- History of severe renal disease (treatment with dialysis or phosphate binders) or hepatic
impairment
- History of organ transplant or stem cell transplant
- Body weight below 60 kg

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-04-2020
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	plaquenil

Generic name:	hydroxychloroquine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	03-04-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-04-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	17-04-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-04-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-04-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-04-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-05-2020

Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-05-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	15-05-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-05-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-06-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
Other	2020-001269-35
EudraCT	EUCTR2020-001269-35-NL
CCMO	NL73589.056.20