Local tolerability of Cyclops dry powder hydrochloroquine inhalation in healthy volunteers; a pilot study

Published: 09-07-2020
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- Primary objective is to assess the local tolerability of dry powder hydroxychloroquine via the Cyclops* at different dosages.- Secondary objective is to investigate systemic pharmacokinetic parameters of dry powder hydroxychloroquine via the...

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

Summary

ID

NL-OMON49136

Source
ToetsingOnline

Brief title
CARRIED-01

Condition

- Viral infectious disorders

Synonym
Corona virus ; COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Corona virus, COVID-19, Dry powder inhalation, SARS-CoV-02

Outcome measures

Primary outcome

The local tolerability of the inhalation of dry powder hydroxychloroquine defined by a drop of forced expiratory volume in 1 second (FEV1) of >15% (lung function measurement) and any other reported adverse events.

For the local tolerability of the inhalation of dry powder hydroxychloroquine the drop of forced expiratory volume in 1 second (FEV1) of >15% (lung function measurement) and any other reported adverse event are all considered critical to decide on proceeding into a phase 2B (and/or a phase 3) trial.

Secondary outcome

The inspiratory parameters during the inhalation maneuver are critical to explore predictors for drug exposure. The following parameters will be calculated: dPmax (maximum pressure drop), Vi (inhaled volume), Ti (total inhalation time), PIF (peak inspiratory flow rate), MIF (mean inspiratory flow rate) and the FIR (average flow increase rate between 20% and 80% of PIF).

Actual inhaled dose (dose minus remainder in inhaler after inhalation) will be calculated and blood samples will be drawn predose, at 0.5, 2 and 3.5 hrs after inhalation.

Study description

Background summary

In this protocol, we will perform a study of the local tolerability of dry powder hydroxychloroquine using the Cyclops* in healthy volunteers. A drop of forced expiratory volume in 1 second (FEV1) of >15 % (lung function measurement) and any other reported adverse events are all considered critical to decide on proceeding into a phase 2B (and/or a phase 3) trial.

Study objective

- Primary objective is to assess the local tolerability of dry powder hydroxychloroquine via the Cyclops* at different dosages.
- Secondary objective is to investigate systemic pharmacokinetic parameters of dry powder hydroxychloroquine via the Cyclops at different dosages.

Study design

single center, ascending dose study

Intervention

not applicable

Study burden and risks

The participants included are healthy volunteers. They will receive three different doses of hydroxychloroquine using the dry powder inhaler (DPI) with (at least) one day in between doses. Before using the dry powder inhaler (DPI), they will receive instructions and their inspiratory flow will be tested. To investigate local tolerability, lung function tests will be performed and the occurrence of adverse events will be scored. Furthermore, before each test dose an indwelling cannula will be inserted and before and after each test dose in total four blood samples will be collected.

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

Healthy volunteer
Age 18-65
Obtained written informed consent

Exclusion criteria

1. Pregnancy or breast feeding
2. Contra-indication to hydroxychloroquine or quinine (Allergic reaction, prolonged QTc-interval (> 450 msec), long-QT syndrome (LQTS), retinopathy, epilepsia, myasthenia gravis, G6PD-deficiency)
3. Concurrent use of amiodarone, ciclosporin, digoxin, erythromycin (daily dose > 1000 mg), ritonavir, sotalol, tamoxifen or tranylcypromine
4. COVID-19 like symptoms, such as fever, couch, or sore throat; only by history taking

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2020
Enrollment:	18
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	hydroxychloroquinesulphate
Generic name:	hydroxychloroquinesulphate
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	09-07-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-08-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2020-001212-17-NL
CCMO	NL73484.042.20