
SOP TITLE: HYDROXYCHLOROQUINE DOSING IN THE COPCOV STUDY
Purpose

This SOP describes the dosing of hydroxychloroquine in the COPCOV study.

Tablets & dose

Hydroxychloroquine is dosed by BASE equivalents

- Hydroxychloroquine sulphate
 - 200 mg of hydroxychloroquine sulphate contains 155 mg hydroxychloroquine BASE

The loading dose is 10 mg/kg of BASE on the first day

Thereafter, one tablet will be given daily.

The loading dose is given to achieve high plasma concentrations so concentrations in the tissues, including the lung, will also be high.

The daily dose will maintain high concentrations over time.

Patients will take the trial medications for 90 days from the blisters they are given by the research team.

Loading dose

Weight based dosing uses the actual body weight.

Well-built muscular individuals with little subcutaneous fat and obese participants will be dosed by their actual weight but the dose is capped at 5 tablets.

Dosing table

Weight kg	Number of tablets	Dose (base) received mg	Dose (base) in mg/kg
40 – <55	3	465	8.61 – 11.63
55 – <70	4	620	8.99 – 11.27
≥ 70	5	775	≤ 11.07

How to give the loading dose

Give the loading dose with food or a snack to reduce upper gastrointestinal symptoms like anorexia, nausea and epigastric discomfort.

Split the dose if giving 4 or 5 tablets:

- 2 tabs then 2 tabs at least 1 hour apart
- 3 tabs then 2 tabs at least 1 hour apart

The second administration does not need to be witnessed.

Side effects

Both drugs are usually well tolerated and side effects tend to be mild and resolve without the need for treatment. Side effects that participants may experience on short term use include:

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- abdominal discomfort
- anorexia
- nausea
- vomiting
- blurred vision/difficulty focusing
- dizziness
- headache
- itching (tends to be more common in individuals of African descent)
- rashes

Management of participants who vomit \leq 30 minutes after the loading dose

For convenience, we only redose after the first dose.

If early vomiting occurs within 30 minutes of the first dose, the dose should be repeated.

Vomiting after this time does not require redosing.

The participant will need to let the research team know so the repeat dose can be given.

The repeat dose should be taken when the participant feels better and when he/she takes his/her next meal.

If vomiting recurs, the participant will be withdrawn from the study because of drug induced vomiting.

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