A multi center open label trial on the safety and efficacy of chloroquine for the treatment of hospitalized patients with laboratory confirmed SARS-CoV-2 infection in Vietnam

Short title: ***The Vietnam COVID-19 trial (The VICO trial)***

PARTICIPANT INFORMATION SHEET

If you are reading this to consider enrolling your relative, please know that whenever this consent refers to 'you' it can be taken to mean "you and/or your relative'.

You are being invited to take part in a research study of treatment therapy for coronavirus disease. This study is funded by Viet Nam Ministry of Health (The Funder). It is being conducted by the Hospital for Tropical Diseases in Ho Chi Minh City, Vietnam and the Oxford University Clinical Research Unit, Vietnam. The sponsor is the University of Oxford.

The study has been approved by the Ministry of Health Research Ethics Committee, Viet Nam and the Oxford Tropical Research Ethics Committee. Please read this information sheet carefully or have someone read it to you. You will be given a copy of this form to keep.

What is the reason for doing the study?

We are conducting this study to find out whether a drug called chloroquine, which has been used widely for the treatment of malaria, may also treat coronavirus illness. This drug has been used for over 50 years mainly to prevent malaria. Chloroquine has been used for several years and appeared to be safe. We would like to study if chloroquine is safe and effective to treat patients infected with the coronavirus.

What will happen if I take part in the study?

If you are eligible and agree to take part in this study, you will be asked to sign two copies of this form and keep one copy for yourself. We will monitor you for 56 days. We will monitor you very carefully during your hospitalization and your follow up visit on day 14, 28, 42 and 56 after your enrolment day in study. We want to see how well you recover after hospital discharge.

According to Viet Nam Ministry of Health Guideline, if you are infected with coronavirus you will need to stay in the hospital until you are recovered and the virus is no longer detected from your throat swabs. During your hospitalization, we will take daily throat swabs to monitor how the drug affects the coronavirus in your body and check your health. We will also take a blood sample (3-5ml) on day 1, day 7 and discharge and day 56. The volume of blood taken is small and will not affect your health.

There are two phases to the study. If you are amongst the first ten patients enrolled, you will receive 10 days of treatment with chloroquine. You will be given the tablets for oral administration. The number of tablets you take will depend on your weight. Your doctor will inform you if you are in this phase of the study.

If you are in the second phase of the study, the possibility you receive chloroquine treatment will be assigned by chance (or 'randomisation'). Half of the people in the study will get chloroquine and half will get no additional treatment. Apart from the chloroquine, everybody will be treated in exactly the same way. Taking part in the study does not affect any other aspect of the health care you will be given.

What are the drug side effects?

Chloroquine is registered for the treatment of malaria or rheumatoid arthritis. It is very safe and well tolerated except the overdose of the drugs. Side-effects are rare but chloroquine taken over a period of years can cause problems with the eyes and can affect eyesight. It is very safe if it is only taken for 10 days, as designed in this study.

Adverse reactions relating to the heart and circulatory system, the central nervous system, the skin, hypoglycaemia, hypersensitivity, stomach, and eyes have all been described after high doses or long duration of treatment. The most common side effect is skin itching, but this is not dangerous and will disappear when the drug is stopped.

If you are pregnant, chloroquine has not been found to be harmful to babies when used at the doses we described. There is no contraindication to breast feeding.

If any new information about the safety of the chloroquine becomes available during the course of this study, we will inform you as soon as possible.

What are the possible risks of taking samples?

You may feel uncomfortable when collecting the throat swab but this feeling goes quickly. Nurses/doctors are trained to be gentle in collecting this kind of samples.

The risks of taking blood sample from the arm include discomfort, occasional bleeding or bruise of the skin at the site of needle puncture, and very rare infection.

What will happen to samples and information?

We will use your swabs and blood samples to look for the presence of the new coronavirus and learn more about how the study drug and your body response to this virus. We will store your samples in the freezer for later testing. These tests will include how your body's immune system responds to the virus and whether your genetic structure affects your ability to catch and recover from the virus.

All the information we collect from you and your samples will be kept confidentially. Only members of the study team can access this information. Your data and samples will only be labelled with unique study ID numbers, which will ensure that nobody will be able to identify who you are.

What are the advantages of taking part/not taking part?

There is no proven benefit for you to join the study. The potential benefit is that chloroquine may be effective in treating your infection. There is a benefit to society by helping us find out as quickly as possible whether this drug works.

The results of the study will improve our understanding and inform us if chloroquine is effective in treating coronavirus infection. The results of this study may provide the first effective drug at treating infection.

You will not have to pay for any costs resulting from your participation in the study. The treatment cost will be covered by the State Budget for treating Covid-19. The drugs and tests, which are parts of this study, will be paid by the study funder. When you come to the clinic for follow-up visits you will be supported for your travel cost. The doctor will explain with you the compensation that you will receive for travelling.

What will happen if you choose not to take part in the study, or if you change your mind after you agree?

Your participation in this study is entirely voluntary. You are free to withdraw from the study at any time and it will not affect the health care service that you can receive.

The study doctor and the study sponsor have rights to withdraw you from this study if it's considered that it is in your best interest.

If you choose not to participate, you will receive standard care per local guidelines. However, your data and samples which were collected for the study up to the time of withdrawal will be used for the study purpose.

Confidentiality

All information about you will be kept confidential. Your medical records will be kept confidential in strict regulation by those who are working on this study and may also be reviewed by the ethics committees and health authorities. Your name will not be used on any of the study documents or on the stored blood samples or in any reports or publications about this study.

The Sponsor is responsible for ensuring the safe and proper use of any personal information you provide, solely for research purposes.

Data protection

The Sponsor is responsible for ensuring personal data you provide is secured and used only for research purposes.

Questions

You are encouraged to ask any questions related to this study during the time of participation. If you have any other questions about the study, its procedures, risks and benefits, or others, please contact: Dr. Nguyen Van Vinh Chau at 0908364657.

If you have any questions about your rights as a subject in this study, you may contact the Ethics Committee at the Hospital for Tropical Diseases at +84 (0) 28 3923 8704.

If you have any general questions, please contact the Clinical Research Unit at +84 (0)28 3924 1983.

Thank you for your time and your consideration to participate in this study.

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INFORMED CONSENT FORM

(Signed by participants ≥18 years old/ or their relative if they lack capacity)

[__]I have read the information given to me OR **[__]** I have someone read to me

- I have been told about the risks and benefits when participating in this study.
- I have had the opportunity to ask questions about this study and these questions have been answered and explained to my satisfaction.
- I understand that I can withdraw from the study at any time and it will not affect the follow-up/treatment for my illness. If I decide to withdraw from the study, I agree that the information and samples collected up to the point I withdraw, may continue to be used.
- I agree that all information collected from me during the study can be made available to others in the future (open access) considering no one can identify me from the details provided.
- I have a copy of this form with all signatures for reference.

Please write the phase of the trial here:…….

☐ **I agree** or ☐ **I do not agree** to be in the study.

If the participant's relative give consent, please tick

☐ **I agree** or ☐ **I do not agree** my relative to participate in the study

Please tick one if you agree to store and use your samples

☐ **I agree** or ☐ **I do not agree** that samples can be used for other future studies, including genetic testing, and that these sample analysis may be conducted outside of Viet Nam if approved by an ethics committee.

Participants

By signing my name here, I confirm what is written above**.**

x_____	x_____	___/____/_____
Participant Signature	Full Name	Date of Signature

Participant's relative

By signing my name here, I confirm what is written above**.**

x_____	x_____	___/____/_____
Relative Signature	Full Name	Date of Signature

For the investigator/ Designee:

I, the undersigned, have fully explained the relevant information of this study to the person named above and will provide her/him with a copy of this signed and dated informed consent form.

x_____	x_____	___/____/_____
Investigator/Designee Signature	Full Name	Date of Signature

For witness: *(If the person giving consent cannot read the form themselves, a witness who is independent of the study must be present and sign here)*: I was present throughout the entire informed consent process with the participant. This form was read accurately to the volunteer, all questions from the volunteer were answered and the volunteer has agreed to take part in the research.

x_____	x_____	_____/_____/_____
Witness Signature	Full Name	Date of Signature