INFORMATION TO PARTICIPANTS INVOLVED IN RESEARCH

You are invited to participate in

The International ALLIANCE COVID-19 Treatment Study

Therapies to prevent progression of COVID-19, including Hydroxychloroquine, Azithromycin, Zinc, Vitamin D, with or without Vitamin C, a multi-centre, international, randomized trial

The study will be conducted by the research team at the National Institute of Integrative Medicine (NIIM), led by Chief Investigators Dr Taufiq Binjemain (Clinical Director, NIIM GC), A/Prof Karin Ried (Director of Research, NIIM), and Prof Avni Sali (Director, NIIM).

Ethics Approval

This research project has been approved by the National Institute of Integrative Medicine Human Research Ethics Committee on 18 May 2020. The HREC Approval no. is [0068N_2020].

Project explanation and objectives

COVID-19 is a global pandemic. So far encouraging results have been shown in different parts of the world with the utilisation of hydroxycloroquine, zinc, and azithromycin, and early studies into some of these, plus some with Vitamin C, have also proven beneficial. Vitamin D levels have also been shown to be an important indicator to the severity of symptoms in COVID-19 patients.

In this randomised trial we aim to assess the effectiveness of an optimal treatment protocol for hospitals to consider in their treatment of COVID-19 patients and their endeavours to save lives.

Aims: In this study, we want to find out, whether the combination of therapies reduces the risk of disease progression in patients with COVID-19

1. Arm 1 Therapies: Hydroxychloroquine, Azithromycin, Zinc, Vitamin D
2. Arm 2 Therapies: Hydroxychloroquine, Azithromycin, Zinc, Vitamin D plus Vitamin C

Who can participate in this study?

1. Patients with symptomatic COVID-19

Exclusion criteria

1) Contra-indication to hydroxychloroquine, azithromycin or Vitamin C: allergy to study interventions, epilepsy, serious hearing or visual problems, advanced liver disease, history of severe depression, calcium oxalate stones, pregnancy or lactating
2) Already receiving chloroquine, azithromycin, >3 grams Vitamin C daily or an experimental antiviral
3) History of fever (e.g. night sweats, chills) and/or acute respiratory infection (e.g. cough, shortness of breath, sore throat) of more than 7 days' duration
4) Calculated creatinine clearance of < 30 mL/minute
5) Baseline ECG showing: QTc ≥470 for males, QTc ≥480 for females
6) Receipt of a drug known to increase QTc: quetiapine, amiodarone, sotalol
7) Known G6PD deficiency, if intravenous Vitamin C (IVC) is to be administered

What will I be asked to do?

You are willing to be randomised to receive either:
Treatment Arm 1: Hydroxychloroquine, Azithromycin, Zinc (Zelenko Protocol) & Vitamin D
Treatment Arm 2: Same as treatment arm 1 plus Vitamin C (oral)

What is the trial treatment?

Hydroxychloroquine (HCQ):	400 mg 1x a day for 1 day
Azithromycin (AZM):	500 mg on day 1 followed by 250 mg once daily for 4 days
Vitamin C:	1 gram 3x times per day (3g/day) for 14 days
Zinc Citrate:	30mg elemental zinc daily for 7-14 days
Vitamin D3:	5,000 IU daily for 14 days (if Vitamin D levels are > 50nmol/l)*
	*Please refer to http://niim.com.au/VitDStudy for Vit D level blood testing

Could the trial medication have any side effects?

Minor side effects:

For outpatients, the doses of HCQ, AZM, Zinc, Vitamin D and oral Vitamin C in the treatment protocol are within the recommended therapeutic range, and have a high safety profile. High doses of oral Vitamin C (> 3-5 gram/ daily) may cause gastrointestinal discomfort and loose stools. Some patients may be sensitive to therapeutic doses of Zinc (> 15mg/day), which may cause nausea. Side effects to be avoided by lowering daily doses.

Serious side effects:

Allergic reactions to any of the treatments are extremely rare. However, if you experience symptoms of a serious allergic reaction including difficulty breathing; closing of your throat; swelling of your lips, tongue, or face; or hives, stop taking the study treatment and immediately seek emergency medical attention.

What will I gain from participating?

While the treatment protocol aims to treat COVID-19 and improve your health and symptoms, you may or may not have any direct benefits. After the study when all data has been collected and analysed, you will be sent a summary of the de-identified study results.

How will the information I give be used?

This study will provide insight into tolerability and effectiveness of the therapies to optimise treatment of COVID-19. The findings will be used for further scientific research. Results will be written up for submission to a peer-reviewed journal.

What are the potential risks of participating in this project?

If symptoms worsen during the study, while on the outpatient treatment protocol, you are encouraged to seek medical care, and contact the research team and doctors.

Privacy and confidentiality

Your personal data will be known only to the study team. All data collected will be de-identified before analysis and stored securely in locked files at the NIIM clinic. No personal data will be divulged in publication.

Who is conducting the study and who should I contact if I have any questions about participating?

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Prof Avni Sali
Director, NIIM

Dr Taufiq Binjemain
Clinical Director, NIIM GC

Queries or complaints

If you wish to discuss with an independent person matters related to making a complaint, or your rights as a participants, contact the Human Research Ethics Committee's Secretary on hrec@niim.com.au.

Trial website:

https://niim.com.au/research-education/the-international-alliance-covid-19-treatment-study

The National Institute of Integrative Medicine Human Research Ethics Committee

STANDARD CONSENT FORM
FOR PEOPLE WHO ARE PARTICIPANTS IN A RESEARCH PROJECT

1. I, …… *(please print name)*

   consent to take part in the research project entitled:

   Therapies to prevent progression of COVID-19, including Hydroxychloroquine, Azithromycin, Zinc, Vitamin D, with or without Vitamin C, a multi-centre, international, randomized trial

2. I acknowledge that I have read the attached Information Sheet entitled:

   The International Alliance COVID-19 Treatment Study

3. I have had the project, so far as it affects me, fully explained to my satisfaction by the research assistant. My consent is given freely.

4. Although I understand that the purpose of this research project is to improve the quality of medical care, it has also been explained that my involvement may not be of any benefit to me.

5. I have been given the opportunity to have a member of my family or a friend present while the project was explained to me.

6. I have been informed that, while information gained during the study may be published, I will not be identified and my personal results will not be divulged.

7. I understand that I am free to withdraw from the project at any time and that this will not affect medical advice in the management of my health, now or in the future.

8. I am aware that I should retain a copy of this Consent Form, when completed, and the attached Information Sheet.

I can be contacted by phone: _____ or by email:_____

My address is: _____

Participant: …… DOB:
(name)

……
(signature) *(date)*

Investigator: ……...
(to be signed at appointment) *(signature)* *(date)*