ISRCTN10207947 https://doi.org/10.1186/ISRCTN10207947

Study of chloroquine/hydroxychloroquine and coronavirus disease (COVID-19) in the healthcare setting

Submission date
20/07/2020

Recruitment status
No longer recruiting

Registration date
21/07/2020

Overall study status
Completed

Last Edited
16/09/2024

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 03/06/2021:
Background and study aims
COVID-19 is a condition caused by the novel coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.

The study team are working to find effective treatments and preventive measures as the pandemic grows. The risks to the healthcare system, as seen with SARS-CoV (SARS) previously, and then in Wuhan with COVID-19, could be a major threat to healthcare operations overall.

Chloroquine has significant antiviral activity against SARS-CoV-2 in laboratory cell culture, as it does for the related SARS-CoV. Several other laboratory studies confirm antiviral activities for chloroquine and hydroxychloroquine. This effect occurred when the drug was given either before or after the virus was added to the cells. This occurs at relatively high concentrations of these drugs when compared to the concentrations needed in the treatment of malaria. However, this concentration of the drugs needed for this effect could be achieved in humans with daily oral (via the mouth) treatment.

Chloroquine has complex properties, and so it is not known what amount of the drug would pass from the bloodstream to the lungs in order to have the necessary concentration to have the intended effect on the virus, although estimates can be made from studies in rats.

Hydroxychloroquine was synthesised first in 1946 and has largely replaced chloroquine for the management of autoimmune diseases as it has slightly reduced adverse effects (as toxicity and damage to the retina of the eyes only occurs at a higher concentration of the drug, and less

abdominal discomfort is associated with the drug). It also has approximately twice the activity of chloroquine against the SARS-CoV-2 virus when inside the human body. Hydroxychloroquine may also cause less itching than chloroquine in dark skinned patients.

The study team think that chloroquine and hydroxychloroquine might both slow viral replication in SARS-CoV-2 exposed patients, therefore reducing or preventing the infection in these patients. even if they are shown not to work in treatment or in post exposure prophylaxis or in treatment. It is a basic principle of infectious diseases that preventing an infection developing requires lower doses or a less active drug than treatment.

In COVID-19 illness the total amount of the virus in the body is far greater than at the time of initial infection. Therefore the window of opportunity for antiviral medicines is at the earliest stages of infection. In addition laboratory studies show that this is when chloroquine and hydroxychloroquine have the greatest anti-viral activity in cells.

The study team believe these drugs may have the greatest use in preventing COVID-19 when given before infection as a preventative measure. These drugs are already in use in the prevention of other diseases, they are low-cost, and have been seen to be safe and well tolerated. If proven to be effective for this purpose, then it would be a readily deployable and affordable preventive measure for healthcare workers.

This study aims to determine if chloroquine or hydroxychloroquine given prior to infection can prevent symptomatic COVID-19 illness. The study will also investigate if there is an effect on the severity of COVID-19 infections, the prevention of asymptomatic COVID-19, and the prevention of acute respiratory infections (ARI) of all causes.

Who can participate?
The population to be studied comprises adult healthcare workers and other persons at risk of contracting COVID-19. These could include nurses, healthcare assistants (HCAs), doctors, pharmacists, physiotherapists, porters and anyone who is at risk of exposure to COVID-19. The study is planning to recruit globally including many countries in UK, Europe, Asia and Africa.

What does the study involve?
The participant will be randomised to receive either a dummy pill or treatment with chloroquine or hydroxychloroquine (the active drug used will vary by study site). Participants will receive a slightly larger amount of the study medication for the first dose and then will take a set amount of either the drug or the dummy pill for 3 months. Participants are followed up for a maximum for 5 months.

What are the possible benefits and risk of participating?
Risks related to chloroquine phosphate/ sulphate/ hydrochloride and hydroxychloroquine sulphate are very low, unless the drug is taken in overdose. These are very safe and generally well-tolerated medications but adverse reactions relating to the cardiovascular system, the central nervous system, the skin, the gastrointestinal (digestive) system, and low blood sugar, hypersensitivity, and retinal (part of the eye) toxicity have all been described. These adverse reactions usually occur after high doses or long-term exposures. Headache and gastrointestinal side-effects (e.g. nausea, diarrhea) are the most common adverse effects. Another adverse effect is itching, in particular with chloroquine, in dark-skinned individuals; Africans are much more commonly affected compared to Asians. These risks will be reduced by excluding participation if people have had a previous serious adverse reaction to chloroquine, or hydroxychloroquine, 4-aminoquinoline compounds, any components of the tablet or retinal or visual field changes of any kind.

Benefits of the study include access to a drug which may potentially prevent or reduce COVID-19 infection. No other proven preventive medication or vaccine exists currently exists or widely-available vaccine around the globe currently exists.

The main potential benefit is to the participant in the chloroquine or hydroxychloroquine arm (direct protection) but individuals in the placebo arm may benefit from indirect protection through the decreased ability of the infection to spread.

Participants should also be aware that their participation may lead to an intervention which may save many lives around the world or, alternatively, may show chloroquine or hydroxychloroquine prevention is ineffective so trials can move on to evaluate other possible drugs with a minimum of delay, and the use of these drugs around the world for this purpose can stop.

Where is the study run from?
Mahidol Oxford Tropical Medicine Research Unit (Thailand)

When is the study starting and how long is it expected to run for?
From April 2020 to March 2022

Who is funding the study?
Wellcome Trust (UK) ACT-Accelerator Therapeutics Partnership

Who is the main contact?
Dr William Schilling
William@tropmedres.ac

Previous plain English summary:
Background and study aims
COVID-19 is a condition caused by the novel coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.

As of writing, SARS-CoV-2 has infected more than 7,000,000 individuals, killed more than 400,000 people and has spread to more than 200 countries and territories.

The study team are working to find effective treatments and preventive measures as the pandemic grows. The risks to the healthcare system, as seen with SARS-CoV (SARS) previously, and then in Wuhan with COVID-19, could be a major threat to healthcare operations overall.

Chloroquine has significant antiviral activity against SARS-CoV-2 in laboratory cell culture, as it does for the related SARS-CoV. Several other laboratory studies confirm antiviral activities for chloroquine and hydroxychloroquine. This effect occurred when the drug was given either before or after the virus was added to the cells. This occurs at relatively high concentrations of these drugs when compared to the concentrations needed in the treatment of malaria. However, this concentration of the drugs needed for this effect could be achieved in humans with daily oral (via the mouth) treatment.

Chloroquine has complex properties, and so it is not known what amount of the drug would pass from the bloodstream to the lungs in order to have the necessary concentration to have the intended effect on the virus, although estimates can be made from studies in rats.

Hydroxychloroquine was synthesised first in 1946 and has largely replaced chloroquine for the management of autoimmune diseases as it has slightly reduced adverse effects (as toxicity and damage to the retina of the eyes only occurs at a higher concentration of the drug, and less abdominal discomfort is associated with the drug). It also has approximately twice the activity of chloroquine against the SARS-CoV-2 virus when inside the human body. Hydroxychloroquine may also cause less itching than chloroquine in dark-skinned patients.

The study team think that chloroquine and hydroxychloroquine might both slow viral replication in SARS-CoV-2 exposed participants, therefore reducing or preventing the infection in these patients. even if they are shown not to work in treatment or in post-exposure prophylaxis or in treatment. It is a basic principle of infectious diseases that preventing an infection developing requires lower doses or a less active drug than treatment.

In COVID-19 illness the total amount of the virus in the body is far greater than at the time of initial infection. Therefore the window of opportunity for antiviral medicines is at the earliest stages of infection. In addition laboratory studies show that this is when chloroquine and hydroxychloroquine have the greatest anti-viral activity in cells.

The study team believe these drugs may have the greatest use in preventing COVID-19 when given before infection as a preventative measure. These drugs are already in use in the prevention of other diseases, they are low-cost, and have been seen to be safe and well-tolerated. If proven to be effective for this purpose, then it would be a readily deployable and affordable preventive measure for healthcare workers.

This study aims to determine if chloroquine or hydroxychloroquine given prior to infection can prevent symptomatic COVID-19 illness. The study will also investigate
if there is an effect on the severity of COVID-19 infections, the prevention of asymptomatic COVID-19, and the prevention of acute respiratory infections (ARI) of all causes.

Who can participate?
Healthcare workers and other staff working in a facility where there are cases of either proven or suspected COVID-19 can participate into the study. Adults from both genders aged less than 65 years will be enrolled in the study. Pregnant women and children are excluded from the study. The study is planning to recruit globally including many countries in UK, Europe, Asia and Africa.

What does the study involve?
The participant will be randomised to receive either a dummy pill or treatment with chloroquine or hydroxychloroquine (the active drug used will vary by study site). Participants will receive a slightly larger amount of the study medication for the first dose and then will take a set amount of either the drug or the dummy pill for 3 months. Participants are followed up for a maximum for 5 months.

What are the possible benefits and risk of participating?
Risks related to chloroquine phosphate/ sulphate/ hydrochloride and hydroxychloroquine sulphate are very low, unless the drug is taken in overdose. These are very safe and generally well-tolerated medications but adverse reactions relating to the cardiovascular system, the central nervous system, the skin, the gastrointestinal (digestive) system, and low blood sugar,

hypersensitivity, and retinal (part of the eye) toxicity have all been described. THese adverse reactions usually occur after high doses or long-term exposures. The main adverse effect is itching, in particular with chloroquine, in dark-skinned individuals; Africans are much more commonly affected compared to Asians.
These risks will be reduced by excluding participation if people have had a previous serious adverse reaction to chloroquine, or hydroxychloroquine, 4-aminoquinoline compounds, any components of the tablet or retinal or visual field changes of any kind.

Benefits of the study include access to a drug which may potentially prevent or reduce COVID-19 infection. No other proven preventive medication or vaccine exists currently exists.

The main potential benefit is to the participant in the chloroquine or hydroxychloroquine arm (direct protection) but individuals in the placebo arm may benefit from indirect protection through the decreased ability of the infection to spread.

Participants should also be aware that their participation may lead to an intervention which may save many lives around the world or, alternatively, may show chloroquine or hydroxychloroquine prevention is ineffective so trials can move on to evaluate other possible drugs with a minimum of delay, and the use of these drugs around the world for this purpose can stop.

Where is the study run from?
Mahidol Oxford Tropical Medicine Research Unit (Thailand)

When is the study starting and how long is it expected to run for?
From April 2020 to April 2021

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Dr William Schilling
William@tropmedres.ac

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2020-001441-39

Integrated Research Application System (IRAS)
282109

ClinicalTrials.gov (NCT)
NCT04303507

Protocol serial number
CPMS 45731, IRAS 282109

Study information

Scientific Title
Chloroquine/ hydroxychloroquine prevention of coronavirus disease (COVID-19) in the healthcare setting; a randomised, placebo-controlled prophylaxis study

Acronym
COPCOV

Study objectives
It is hypothesised that chloroquine and hydroxychloroquine might both slow viral replication in exposed participants, attenuating or preventing the infection even if they are shown not to work in treatment or in post-exposure prophylaxis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/03/2020, Oxford Tropical Research Ethics Committee (OxTREC) (Research Services, University of Oxford, University Offices, Wellington Square, Oxford OX1 2JD; +44(0)1865 (2) 82106; oxtrec@admin.ox.ac.uk), ref: 25-20

Study design
Multi-centre double-blind randomized placebo-controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions

Current interventions as of 03/06/2021:
The study is a double-blind, randomised, placebo-controlled trial that will be conducted primarily in healthcare settings and other facilities directly involved in COVID-19 case management. We will recruit healthcare workers and other persons at risk of contracting COVID-19, who can be followed reliably for 5 months.

The participant will be randomised to receive either chloroquine or placebo (1:1 randomisation), or to hydroxychloroquine or placebo (1:1 randomisation). A loading dose of 10mg base/kg (four 155 mg tablets for a 60 kg subject), followed by 155 mg daily (250 mg chloroquine phosphate salt/ 200 mg hydroxychloroquine sulphate) will be taken for 3 months.

A randomisation list will be prepared by a statistician using block randomisation in a 1:1 ratio for the chloroquine/ hydroxychloroquine arm versus the placebo and stratified by site. The randomisation will be computer-generated and programmed in Stata 15.

Previous interventions:
The study will be conducted in healthcare settings and other facilities directly involved in COVID-19 case management. We will recruit healthcare workers and other staff working in a facility where there are cases of either proven, or suspected COVID-19, who can be followed reliably for 5 months.

The participant will be randomised to receive either chloroquine or placebo (1:1 randomisation), or to hydroxychloroquine or placebo (1:1 randomisation). A loading dose of 10 mg base/kg (between three and five tablets e.g., four 155-mg tablets for a 60-kg subject), followed by 155 mg daily (250 mg chloroquine phosphate salt/200 mg hydroxychloroquine sulphate) will be taken for 3 months.

A randomisation list will be prepared by a statistician using block randomisation in a 1:1 ratio for the chloroquine/ hydroxychloroquine arm versus the placebo and stratified by site. The randomisation will be computer-generated and programmed in Stata 15.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Current drug name(s) as of 03/06/2021: Chloroquine and hydroxychloroquine will be in the dose of 155 mg chloroquine base (250 mg of chloroquine phosphate or 200 mg of hydroxychloroquine sulphate) It is expected that chloroquine will be used in Asian sites and hydroxychloroquine in Europe and Africa, specific drug allocation will be determined by each participating country. Hydroxychloroquine sulphate will be used in the UK. Previous drug name(s): Chloroquine and hydroxychloroquine will be in the dose of 155 mg chloroquine base (250 mg of chloroquine phosphate or 200 mg of hydroxychloroquine sulphate) It is expected that chloroquine will be used in Asian sites and hydroxychloroquine in Europe, specific drug allocation will be determined by each participating country. Hydroxychloroquine sulphate will be used in the UK.

Primary outcome(s)

The number of symptomatic COVID-19 infections will be compared between participants randomised to chloroquine or hydroxychloroquine, and placebo groups between baseline and 90 days

Key secondary outcome(s))

Current secondary outcome measures as of 28/01/2022:
Secondary outcome measures
1. The symptoms severity and duration of COVID-19 illness, in those who become infected during the study will be compared between the two groups using a respiratory severity score between baseline and 90 days.
2. The number of asymptomatic cases of COVID-19 will be determined by comparing serology in all participants at time of enrolment and at the end of follow up.
3. The number and severity of symptomatic acute respiratory illnesses will be compared in participants randomised to chloroquine or hydroxychloroquine, and placebo groups between baseline and 90 days.

Tertiary outcome measures
1. Genetic loci and levels of biochemical components will be correlated with occurrence of and disease severity of COVID-19 or other Acute Respiratory Infections (ARIs) between baseline and 90 days.
2. The days lost to work, and the relationship between the subjective assessment of wellbeing and the decision to self-isolate when unwell (i.e. not go to work) will be examined in relation to infection and treatment arm between baseline and 90 days.
3. The trial will collect data on use of health care resources and health related quality of life (EQ-5D-3L) to determine the effects between treatment groups between baseline and 90 days.

Previous secondary outcome measures as of 03/06/2021:
Secondary outcome measures
1. The symptoms severity and duration of COVID-19 illness, in those who become infected during the study will be compared between the two groups using a respiratory severity score between baseline and 90 days.
2. The number of asymptomatic cases of COVID-19 will be determined by comparing serology in all participants at time of enrolment and at the end of 5 months.
3. The number and severity of symptomatic acute respiratory illnesses will be compared in participants randomised to chloroquine or hydroxychloroquine, and placebo groups between baseline and 90 days.

Tertiary outcome measures
1. Genetic loci and levels of biochemical components will be correlated with occurrence of and disease severity of COVID-19 or other Acute Respiratory Infections (ARIs) between baseline and 90 days.
2. The days lost to work, and the relationship between the subjective assessment of wellbeing and the decision to self-isolate when unwell (i.e. not go to work) will be examined in relation to infection and treatment arm between baseline and 90 days.
3. The trial will collect data on use of health care resources and health related quality of life (EQ-5D-3L) to determine the effects between treatment groups between baseline and 90 days.

Previous secondary outcome measures:
1. The symptoms severity and duration of COVID-19 illness, in those who become infected during the study will be compared between the two groups using a respiratory severity score between baseline and 90 days

2. The number of asymptomatic cases of COVID-19 will be determined by comparing serology in all participants at time of enrolment and at the end of 5 months
3. The number and severity of symptomatic acute respiratory illnesses will be compared in participants randomised to chloroquine or hydroxychloroquine, and placebo groups between baseline and 90 days

Tertiary outcome measures
1. Genetic loci and levels of biochemical components will be correlated with occurrence of and disease severity of COVID-19 or other Acute Respiratory Infections (ARIs) between baseline and 90 days
2. The days lost to work, and the relationship between the subjective assessment of well-being and the decision to self-isolate when unwell (i.e. not go to work) will be examined in relation to the infection and treatment arm between baseline and 90 days
3. Monetary costs associated with the use of healthcare resources between baseline and 90 days
4. Health-related quality of life measured using the quality of life questionnaire (EQ-5D-3L) at baseline and 90 days

Completion date
21/03/2022

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 03/06/2021:
1. Participant is willing and able to give informed consent for participation in the study and agrees with the study and its conduct
2. Agrees not to self-medicate with chloroquine, hydroxychloroquine or other potential antivirals
3. Adults (exact age is dependent on countries) less than 70 years old at the time of consent
4. Not previously diagnosed with COVID-19
5. Not currently symptomatic with an ARI
6. Participant is a healthcare worker or is a person at risk of contracting COVID-19.
7. Possesses an internet-enabled smartphone (Android or iOS)

Previous participant inclusion criteria:
1. Willing and able to give informed consent for participation in the study and agrees with the study and its conduct
2. Agrees not to self-medicate with chloroquine, hydroxychloroquine or other potential antivirals
3. Adults (exact age is dependent on countries) <70 years old at the time of consent
4. Not previously diagnosed with COVID-19
5. Not currently symptomatic with an ARI
6. Working in a facility where there are cases of either proven or suspected COVID-19
7. Possesses an internet-enabled smartphone (Android or iOS)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Upper age limit
70 years

Sex
All

Total final enrolment
4646

Key exclusion criteria
Current participant exclusion criteria as of 03/06/2021:
1. Hypersensitivity reaction to chloroquine, hydroxychloroquine or 4-aminoquinolines
2. Contraindication to taking chloroquine as prophylaxis e.g. known epileptic, known creatinine clearance <10 ml/min
3. Already taking chloroquine, hydroxychloroquine or 4-aminoquinolines, or history of these medications within the previous 7 days
4. Taking any of the following prohibited medications:
4.1. Antiarrhythmic medications: digoxin, amiodarone, sotalol, flecainide
4.2. Antiparasitic/malarial agents: mefloquine, halofantrine, praziquantel
4.3. Antibiotics: levofloxacin, moxifloxacin, ciprofloxacin, azithromycin, clarithromycin, erythromycin
4.4. Antifungal drugs: fluconazole, ketoconazole, itraconazole, terfenadine
4.5. Psychoactive drugs: lithium, quetiapine, chlorpromazine, thioridazine, ziprasidone, haloperidol, droperidol, methadone
4.6. Migraine treatment: sumatriptan
4.7. Antihistamines: astemizole
4.8. Antiemetics: prochlorperazine, metoclopramide
4.9. Cancer treatments: abiraterone, dabrafenib, dacomitinib, enzalutamide, idelalisib, mitotane
4.10. Other specific drugs: ciclosporin, conivaptan, agalsidase alfa or beta, mifepristone, stiripentol
5. Known retinal disease
6. Inability to be followed up for the trial period
7. Known prolonged QT syndrome (however ECG is not required at baseline)
8. Known pregnancy or women who are actively trying to become pregnant
9. Prior diagnosis of porphyria
10. Previously received any dose of COVID-19 vaccine
11. The investigator may consult the physician’s guidance documents for any further questions regarding the eligibility of potential participants.

Previous participant exclusion criteria:
1. Hypersensitivity reaction to chloroquine, hydroxychloroquine or 4-aminoquinolines
2. Contraindication to taking chloroquine as prophylaxis e.g. known epileptic, known creatinine clearance <10 ml/min
3. Already taking chloroquine, hydroxychloroquine or 4-aminoquinolines
4. Taking a concomitant medication
5. Known retinal disease
6. Inability to be followed up for the trial period
7. Known prolonged QT syndrome (however ECG is not required at baseline)
8. Known pregnancy or women who are actively trying to become pregnant
9. Prior diagnosis of porphyria

Date of first enrolment
29/04/2020

Date of final enrolment
21/12/2021

Locations

Countries of recruitment
United Kingdom

England

Benin

Ethiopia

Indonesia

Kenya

Lao People's Democratic Republic

Mali

Niger

Pakistan

Thailand

Zambia

Study participating centre
Brighton and Sussex University Hospitals
Brighton
United Kingdom
BN2 5BE

Study participating centre
Oxford University Hospitals NHS Foundation Trust
Oxford
United Kingdom
OX3 9DU

Study participating centre
Imperial College Healthcare NHS Foundation Trust
London
United Kingdom
W2 1NY

Study participating centre
The Aga Khan University Hospital
Karachi
Pakistan
74800

Study participating centre
Faculty of Tropical Medicine, Mahidol University
420/6 Ratchawithi Road, Ratchathewi
Bangkok
Thailand
10400

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
University Hospitals of Morecambe Bay NHS Trust
Kendal
United Kingdom
LA9 7RG

Study participating centre
The Dudley Group NHS Foundation Trust
Dudley
United Kingdom
DY1 2HQ

Study participating centre

Birmingham & Solihull Mental Health NHS Trust
Birmingham
United Kingdom
B1 3RB

Study participating centre
Rotherham, Doncaster And South Humber NHS Foundation Trust
Doncaster
United Kingdom
DN4 8QN

Study participating centre
Zambart
P.O. Box 50697
Lusaka
Zambia
-

Study participating centre
Murni Teguh Memorial Hospital
North Sumatra
Indonesia
20231

Study participating centre
Bunda Thamrin Hospital
North Sumatra
Indonesia
20112

Study participating centre
Airlangga University Hospital (UNAIR)
East Java
Indonesia
60115

Study participating centre
Husada Utama Hospital
East Java

Indonesia
60131

Study participating centre
Sardjito Hospital
Yogyakarta
Indonesia
55281

Study participating centre
Centre Hospitalier et Universitaire de Zone Abomey-Calavi
Abomey-Calavi
Benin
-

Study participating centre
Mbagathi County Hospital
P.O. Box 40205-00200
Nairobi
Kenya
-

Study participating centre
Fountain Healthcare Hospital
P.O Box 5819-30100
Eldoret
Kenya
-

Study participating centre
Niamey (Epicentre France)
Maradi
Niger
BP 13330

Study participating centre
B.P. Koirala Institute of Health Sciences
Buddha Road
Dharan

Nepal
56700

Study participating centre
Hospital De Zone Allada
P45J+455
Allada
Benin
BP 559

Study participating centre
University Hospital Center of Angre
Abidjan
Côte d'Ivoire
BP 54378

Study participating centre
University Hospital Center of Bouake
Bouake
Côte d'Ivoire
BP 1174

Study participating centre
The Bamako Hospital of Dermatology
Djicoroni Para
Avenue Mohamed VI
Bamako
Mali
BP 251

Study participating centre
Hospital Of Mali
Missabougou Bamako
Bamako
Mali
BP 3333

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Funder Name

Mastercard Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
With the participant's consent, clinical data and results from blood analyses stored in the database may be shared according to the terms defined in the MORU data sharing policy with other researchers to use in the future.

Data generated from this study will adhere to the 2016 Statement on data sharing in public health emergencies (https://wellcome.ac.uk/press-release/statement-data-sharing-public-health-emergencies).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/09/2024	16/09/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 6.0	13/01/2021	19/10/2022	No	No
Statistical Analysis Plan	version 1.0	10/12/2022	27/07/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes