ISRCTN90437126 https://doi.org/10.1186/ISRCTN90437126

Study on the effects of using ivermectin to prevent COVID-19 in an adult population in Brazil

Submission date
11/11/2020

Recruitment status
No longer recruiting

Registration date
17/11/2020

Overall study status
Completed

Last Edited
24/02/2022

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English Summary

Background and study aims
COVID-19 is a condition caused by the 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.

In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of March 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.

Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.

To date, some 12.9% of global deaths occurred in Brazil.

Ivermectin has been shown strong antiviral activity against chikungunya virus in 2016. Ivermectin is approved to treat a range of parasitic worm infections, it is a safe drug widely used in many countries and presents very few and mild side effects. The aim of this study is to test if taking ivermectin can reduce the probability of being infected by SARS-CoV-2 virus that causes COVID-19.

Who can participate?
Adult volunteers aged 18 or more who live in a local community previously chosen, who have neither developed immunity for SARS-CoV-2 or COVID-19 and are clinically asymptomatic for COVID-19.

What does the study involve?
Healthy volunteers will be randomly allocated to one of the two groups.
Those in the first group will receive a single dose of a placebo (dummy drug) and those in the second group receive a single dose of ivermectin. The follow-up period is 90 days after receiving the treatment.

Participants will be asked to provide information regarding to presence of symptoms suggestive of COVID-19 at any point during the 90 days of the trial. All participants will be interviewed before they have taken their treatment dose and after, at days 7, 14, 30 and 90, to answer if they have presented any signs and/or symptoms of COVID-19 and side effects, that will be included in the questionnaire of this trial.
They will be asked to provide fingerpick blood samples for testing immunity status for SARS-CoV-2 at time of enrollment (screening for excluding previous infected participant) and at any time of follow-up to confirm any symptom suggestive of COVID-19.

What are the possible benefits and risks of participating?
The study participants might help be diagnosed early and treated for COVID-19. Participants who do not respond to treatment and develop symptoms of COVID-19 will be referred to local health facilities for confirmatory diagnoses and receive treatment (according to WHO recommendations).
There is a low risk of side effects of ivermectin. These will be monitored throughout.

Where is the study run from?
Centro Odontomédico (Brazil)

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

Who is funding the study?
Governmental funds are provided by the city of Mamanguape (Paraíba, Brazil) running by the health secretary of the city and the private resources by the Institute of Clinical Research Scinet, Recife, Pernambuco, Brazil.

Who is the main contact?
Prof. Taciana Castro
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IvermecPrev-Brazil ScinetN001.2020

Study information

Scientific Title
Investigation of efficacy and safety for Preventing COVID-19 using a single dose of Ivermectin (IvermecPrev-Brazil) in the general asymptomatic susceptible population under SARS-CoV-2 exposition during a pandemic period in Brazil: randomized double-blind placebo-controlled trial

Acronym
IvermecPrev-Brazil

Study hypothesis

A single dose of ivermectin plus usual health prophylaxis recommendations significantly reduces the number of new COVID-19 cases in the community compared to prophylaxis recommendations alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/06/2020, National Commission for Research Ethics (CONEP) (Ministério da Saúde - Esplanada dos Ministérios Edifício Anexo Bl. G Ala B Sl. 13-B, 70.058-900, Brasíl; +55 61 3315-295; conep@saude.gov.br), ref: 31523220.0.1001.0008

Study design
Two-armed randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Condition
Prevention of COVID-19 (SARS-CoV-2 infection)

Interventions
Study participants eligible for treatment will be randomly assigned to receive single, oral doses of placebo or ivermectin using a computer-generated stratified block randomization code. The random allocation sequence with varying random blocks will be provided by an independent pharmaceutic.

To those allocated in the intervention arm, ivermectin will be used as a single dose of 400 µg/kg and to those allocated in the control arm a dummy drug (placebo) of identic appearance from a sealed opaque envelope . Participants, researchers and community health workers are all blinded regarding treatment or placebo arm. The treatment will be administered on one day only and follow up will be conducted for all treatment arms 90 days after treatment.

Intervention Type
Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)
Ivermectin

Primary outcome measure
Covid-19 case diagnosis (conversion from being asymptomatic pre-treatment to symptomatic post-treatment for COVID-19) by using a questionnaire for screening clinical symptoms of COVID-19, at baseline, and during the follow up at 7, 14, 30 and 90 days . All clinically diagnosed COVID-19 cases will be confirmed by serologic IgM and IgG anti-SARS-CoV2 test at 14 days post-initial symptoms.

Secondary outcome measures
1. Clinical status of COVID-19 using the WHO Clinical Progression Scale measured at 14 and 30 days after COVID-19 diagnosis (if applicable)
2. Incidence of severe COVID-19 cases determined by active cases detection and defined by WHO Clinical Progression Scale at days 14 and 30 after treatment
3. Rate of adverse events using active case detection with questionnaire and adverse events grades (mild, moderate and severe) using Common Terminology Criteria for Adverse Events (CTCAE) v5.0 at days 2 and 7 after treatment
4. Hospitalization rate at 7,14, 30 and 90 days measured using patient records
5. Deaths at the follow-up period (90 days) measured using patient records

Overall study start date
10/04/2020

Overall study end date
30/08/2022

Eligibility

Participant inclusion criteria
1. Adult participants susceptible to be infected by SARS-CoV-19 (not previous infection) tested negative for IgM and IgG immunological test
2. No symptoms of COVID-19
3. Written informed consent signed by participating for the study

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
The target total recruitment of participants for the trial is 800 adults, 400 in each arm.

Participant exclusion criteria

1. Pregnant or breastfeeding
2. Known allergy to study medications used at intervention
3. Known or reported history of liver disease
4. Use of coumarin (anticoagulant)

Recruitment start date
15/09/2020

Recruitment end date
25/02/2022

Locations

Countries of recruitment
Brazil

Study participating centre
Centro Odontomédico
Rua Aristides Lobo, S/N - Centro
Mamanguape - Paraíba
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58280-000

Study participating centre
Unidade de Saúde Santa Edwirgens
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Sponsor information

Organisation
Federal University of Pernambuco

Sponsor details
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Sponsor type
Research organisation

Website
https://www.ufpe.br/lika/equipe

ROR
https://ror.org/047908t24

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Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
Clinical Research Institute Scinet

Funder Name
Mamanguape's Health Secretariat

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
15/09/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
What data in particular will be shared?
Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).
What other documents will be available?
Study Protocol
When will data be available (start and end dates)?
Beginning 3 months and ending 36 months following article publication.
With whom?
Researchers who provide a methodologically sound proposal.
For what types of analyses?
To achieve aims in the approved proposal. For individual participant data meta-analysis
By what mechanism will data be made available?
Proposals may be submitted up to 36 months following article publication. After 36 months the data will be available in our University's data warehouse but without investigator support other than deposited metadata. Information regarding submitting proposals and accessing data may be found at (Link to be provided).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		24/02/2022	24/02/2022	No	No
Protocol file	Protocol supplement	24/02/2022	24/02/2022	No	No