ISRCTN40302986 https://doi.org/10.1186/ISRCTN40302986

Does ivermectin cure and/or prevent COVID-19?

Submission date
23/04/2020

Recruitment status
No longer recruiting

Registration date
26/05/2020

Overall study status
Completed

Last Edited
23/03/2021

Condition category
Infections and Infestations

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

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 April 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.
Ivermectin is a drug that has been in use for over three decades for the treatment of river blindness in Africa. Recently studies in Australia suggest that it is very active in laboratory conditions at eliminating the COVID-19 RNA virus, reducing viral loads by a factor of 5000. This study aims to determine whether ivermectin is equally effective in infected patients and if so, is it safe, and what are the optimal doses? The researchers are also interested to know at what phase of the illness it is most useful - as prevention, in the early phase of the illness, or in the late stages. If it is found to be effective, it could be a game-changer in how sick people are treated, essentially with two to six tablets, or even in how populations are prevented from getting the disease.

Who can participate?
All patients who are positive for the COVID-19 virus can participate except for pregnant women in the first trimester and those who withhold consent

What does the study involve?
The study involves the giving out of tablets of ivermectin in different doses to two groups of

patients, and a placebo or ineffectual lookalike tablet to a third group. The researchers will then measure how this affects the viral load over a period of 2 weeks. They will also monitor the patients clinically to see what effect the drug has on the clinical progression of the disease.

What are the possible benefits and risks of participating?
Participation is a contribution to further knowledge of the disease and how it can be treated or prevented. It is hoped that the tablet will be of benefit to cure or shorten the duration of the disease. As to the risk of participation, ivermectin is a very safe drug. About 165 million Africans have been treated with the drug over the past 30 years and only less than 300 have developed any serious adverse effects, especially if they have concomitant loiasis (African eye worm). In that case, they can develop encephalopathy (damage that affects the brain). Otherwise, reactions are generally mild and may include itching, headache, vomiting, tiredness, and loss of appetite.

Where is the study run from?
Lagos University Teaching Hospital (Nigeria)

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

Who is funding the study?
Rachel Eye Center (Nigeria)

Who is the main contact?
Prof. Femi Babalola
Bablo57@gnail.com

Contact information

Type(s)
Scientific

Contact name
Prof Olufemi Babalola

Contact details
23 Onitsha Crescent
Garki II
Abuja
Nigeria
4108
+234 (0)8098603395
bablo57@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A double-blind clinical trial to repurpose and assess the efficacy and safety of ivermectin in COVID-19

Acronym
IVERCOVID

Study objectives
Ivermectin significantly reduces COVID-19 viral load.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/06/2020, Lagos University Teaching Hospital ethics committee (Prof. Njideka Okubadejo, Department of Medicine, College of Medicine, University of Lagos, Lagos, Nigeria; +234 (0)1 5850737, 5852187; hrecluth@gmail.com, njide_okubadejo@yahoo.com), ref: NAF/DER/CT/IVERCOVID/2020

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions

This will be a randomized parallel-group study of three groups of COVID-positive Nigerian patients with 10 - 15 post-exposure COVID-positive subjects in each treatment arm. There shall be three treatment groups allotted by randomization.

A. 10 - 15 patients receive ivermectin 6 mg twice a week for 2 consecutive weeks (hour 0 and hour 84 or 3.5 days)
B. 10 - 15 patients receive Ivermectin 12 mg twice a week for 2 consecutive weeks (hour 0 and hour 84 or 3.5 days)
C. 10 - 15 patients receive a matching inactive placebo from a pharmacist who will not be part of the treatment team

Randomization: The researchers hope to employ a standard clinical pharmacological randomization tool.
Sequential patients will be assigned by chance to one of three treatments, A, B, or C (ratio 1:1:1), by random numbers or asking the patient to select from A B or C labelled papers or balls. This sequence shall be followed until the convenient sample of 10 - 15 is attained in each of the three groups.

The total duration of follow up will be about 4 weeks after dosing in the first instance but long-term follow-up will continue as the clinical situation dictates.

Intervention Type
Drug

Phase
Phase III

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

Primary outcome measure
Viral RNA load measured using quantitative branched DNA (bDNA), reverse transcriptase-polymerase chain reaction (RT-PCR), and qualitative transcription-mediated amplification at baseline and 1, 2, 4, 7, 10, 12, 14 days

Secondary outcome measures
Measured on days 0, 2, 4, 7, 10, 12, 14:
1. Body temperature measured using infrared temperature sensor
2. Heart Rate measured using a pulse oximeter device
3. Respiratory rate measured using respiratory movement method
4. PaO2 measured using pulse oximeter
5. Symptom checklist especially:
5.1. Anosmia/cacosmia measured using University of Pennsylvania Smell Identification Test
5.2. Respiratory: cough frequency, intensity, dyspnea measured using Likert scale
5.3. GIT symptoms: nausea, vomiting, diarrhoea, abdominal pain, blood in stool or vomit, depending on reports taken from the patient and observations by the nurse over the past 24 hours
5.4. Genitourinary system: dysuria, urine colour, frothiness measured using reports taken from patient and observations by the nurse over the preceding 24 hours
5.5. Cardiovascular system: chest pain, palpitations, tiredness, lassitude, dyspnea on exertion measured using reports taken from the patient and observations by the nurses

5.6. Central nervous system: headache, as reported by the patient, and change in consciousness level as measured using the Glasgow Coma Scale

Overall study start date
23/04/2020

Completion date
06/10/2020

Eligibility

Key inclusion criteria
1. COVID-positive people
2. All ages and genders
3. Informed consent given after Emergency IRB approval

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
10-15 per arm totalling 45 maximum

Total final enrolment
62

Key exclusion criteria
1. COVID-negative people
2. Those who refuse to give informed consent
3. Pregnant women in first trimester of pregnancy

Date of first enrolment
22/06/2020

Date of final enrolment
22/09/2020

Locations

Countries of recruitment
Nigeria

Study participating centre

Lagos University Teaching Hospital
Ishaga Road, Idi Araba
Lagos
Nigeria
100254

Sponsor information

Organisation
Lagos University Teaching Hospital

Sponsor details
Ishaga Road, Idi Araba
Lagos
Nigeria
100254
+234 (0)8057344994
cobode@yahoo.com

Sponsor type
Hospital/treatment centre

Website
http://www.luth.org.ng

ROR
https://ror.org/00gkd5869

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Rachel Eye Center

Results and Publications

Publication and dissemination plan
The researchers will make additional documents including the protocol available as soon as they are finalised.

The researchers hope to publish their results in peer-reviewed journals such as the Nigerian Medical Journal, National Postgraduate medical journal and the Lancet. They will also describe their results to the lay public through the news media.

Intention to publish date
10/11/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Femi Babalola (Bablo57@gmail.com). Anyone who is interested in analyzing the data is welcome to have a look at it provided the original authors are included in whatever publication emanates from such.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/02/2021	23/03/2021	Yes	No