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A study investigating cocoa powder as an additional treatment for coronavirus patients and its effect on complications associated with COVID-19

Submission date
21/12/2021

Recruitment status
No longer recruiting

Registration date
24/12/2021

Overall study status
Completed

Last Edited
20/06/2022

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
A new disease (COVID-19), caused by a germ (virus) called the coronavirus (SARS-CoV-2), is spreading around the world (this is called a pandemic). The illness is usually mild, but it can cause a severe chest infection (pneumonia) and other complications and result in hospitalization in some people. It has been found that a high percentage of COVID-19 patients experience disturbances related to the ability of their blood to form clots appropriately. It has also been found out that these disturbances in clotting are related to the function of a portion in the lining layer in all blood vessels (endothelial layer), and which regulates the exchange of important nutrients between the blood and its surroundings. It has been noted that certain compounds called polyphenols, which are found in certain plants including cocoa, are able to 'repair' damage to the blood vessel lining.

Polyphenol-rich cocoa is a strong anti-oxidant with reported benefits in improving endothelial function. By administering polyphenol-rich cocoa powder in addition to standard treatment to patients affected by COVID-19 it is thought that complications of COVID-19 could be less severe.

Who can participate?
All patients with confirmed COVID-19 (using a swab of the nose and throat on hospital admission) seeking care at Ga East Municipal Hospital.

What does the study involve?
Participants invited to take part in this study will be invited to read and sign a consent form indicating their willingness to be enrolled in the study. The scientists and investigators running the study will ask further questions to confirm that this study is appropriate for participants.

The study has two different groups: one group will receive the natural cocoa beverage twice a day over 14 days (or until discharge from hospital) in addition to standard COVID-19 treatment and the other group will receive the standard treatment only. Participants will be placed into

one of 2 treatment groups in a similar way to flipping a coin, they have an equal chance of being put in either of the groups. Participants will not be able to choose which group you are placed in. Participants will be assessed as part of their stay in hospital and this information will be used to understand the effect of the natural cocoa beverage in addition to standard COVID-19 treatment.

What are the possible benefits and risks of participating?
Unwanted effects are not anticipated as cocoa is used widely by most people as a beverage. The study team will to record if any unanticipated effects do occur when the cocoa beverage is used as a beverage during COVID-19 treatment.
The information collected as part of his study will be used to assess the suitability of the addition of cocoa on recovery or otherwise from COVID-19.

Where is the study run from?
Ghana Cocoa Board (Ghana)

When is the study starting and how long is it expected to run for?
January 2022 to September 2022

Who is funding the study?
Ghana Cocoa Board (Ghana)

Who is the main contact?
Dr Edward Amporful
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Polyphenol-rich cocoa powder as adjuvant therapy in patients with COVID-19

Study objectives
Polyphenol-rich cocoa powder as adjuvant therapy in patients with COVID-19 reduces complications associated with COVID-19

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/10/2021, Research & Development Division, Ghana Health Service (P. O. Box MB 190, Accra, Ghana; + 233-302-681109; ethics.research@ghsmail.org), ref: GHS-ERC:012/09/21

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Prevention

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

Interventions
A total of 126 consenting participants will be recruited and randomly assigned in a 1:1 ratio to one of two groups as follows:
1. The treated group will, in addition to standard treatment for COVID-19, receive 10 g of polyphenol-rich natural cocoa powder pre-(packed in plastic dispensing envelopes) twice daily for 14 days or until discharge. The powder will be dissolved in 200 ml of boiling water, stirred, allowed to cool, and then administered at a temperature tolerable to the patient, 1 h before meals.
2. The comparison group will receive only the standard treatment for COVID-19

Participants will be randomized through consecutive allocation of study subject numbers and an enrolment log prepared in advance by the study statistician.

Vital signs and other clinical information will be assessed twice daily 14 days or until discharge for all recruited participants.

Intervention Type
Supplement

Primary outcome(s)
1. COVID-19 symptoms measured using clinical assessment twice daily between baseline and 14 days, or until discharge
2. Coagulation measured using laboratory assessment of blood samples collected twice daily between baseline and 14 days, or until discharge

Key secondary outcome(s)
1. SARS-CoV-2 viral load measured using RT-PCR at baseline and 96 h
2. Duration of hospital admission measured using from patient records between baseline and

hospital discharge
3. Time to clinical recovery measured using from patient records between baseline and hospital discharge
4. Final clinical prognosis measured using measured from patient records at 14 days or hospital discharge
5. Need for ICU management measured from patient records between baseline and hospital discharge
6. Endothelial function measured using biomarkers of coagulation on laboratory assessment and improvement in symptoms on clinical assessment twice daily between baseline and 14 days, or until discharge

Completion date
21/09/2022

Eligibility

Key inclusion criteria
1. Confirmed COVID-19 at admission (real-time RT-PCR-documented SARS-CoV2-carriage in nasopharyngeal sample) and seeking care at the study sites
2. Can tolerate oral medication and oral food intake
3. Able to sign a written informed consent form (or assent and parental consent in the case of those below 18 years of age)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Total final enrolment
126

Key exclusion criteria
1. Unable to swallow/receive oral medication
2. Requiring ICU care on screening
3. Pregnant or lactating, based on their declaration and pregnancy test results when required
4. Self-reported known allergies or intolerance to natural cocoa
5. Inability or unwillingness to be followed up for the trial period

Date of first enrolment
21/06/2022

Date of final enrolment
15/09/2022

Locations

Countries of recruitment
Ghana

Study participating centre
Ga East Municipal Hospital
Ghana Infectious Disease Centre
Accra
Ghana
0302

Sponsor information

Organisation
Ghana Cocoa Board

Funder(s)

Funder type
Other

Funder Name
Ghana Cocoa Board

Results and Publications

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. George Obeng Adjei (goadjei@yahoo.com).

IPD sharing plan summary
Available on request