Response to Covid-19 in Africa; Discovered March 2020

Zelalem Kiros Bitsue Ph.D. Immunologist
Owner, Founder and General Director
United States of African Health Organization (US-AHO),
South Africa

Dr. Martha Fekadu Rahmetho, MD,
Internist, Internal Medicine, Head of Department
St. Peter Specialized Hospital

US-AHO
United States of Africa Health Organization

17 November, 2020

Phase IIb/III Studies of Immuno-modulatory and Inhibitory AZEE in the COVID-19 with Co- morbid illness Patients

Phase IIb/III Studies of Immuno-modulatory and Inhibitory in the COVID-19 with Co- morbid illness meeting

US-AHO

Zelalem Kiros Bitsue Ph.D. Immunologist
Owner, Founder and General Director
United States of African Health Organization (US-AHO),
17 November, 2020

Phase IIb/III Studies of Immuno-modulatory and Inhibitory AZEE in the COVID-19 with Co- morbid illness Patients

United States of African Health Organization (US-AHO)

Memorandum and Articles of organization of The United States of African Health Organization (US-AHO) (Pty) Ltd 2014/006864/07

The Above Company has been registered in terms of section 14 of the Companies Act, 2008 RSA.

Body corporate

The organization shall:

- Exist in its own right, separately from its members.
- Continue to exist even when its membership changes and there are different office bearers.
- Be able to own property and other possessions.
- Be able to sue and be sued in its own name.
- Not having any share capital

Mission and vision

- United States of Africa Health Organization "US-AHO" founded on the belief that mainly aimed at economy development

- Making Africa an Economic Impact/Influence in the World

Professional Achievement

I open my own doors. When my peers give up, I go on. I have self-belief. I believe that I can make a difference to an organization; university; research institution; company; a client; and a colleague. I am committed to success and I am determined to achieve all *my goals*.

While studding undergraduate, I stood out, discovered Malaria vaccine to cure Plasmodium Falciparum, to make world malaria free particularly Africa

Whilst working in at Governmental Hospital I stood out, established United States of Africa Health Organization. Within months, it had become so successful that a specific Health Organization was created for the very first time in the region.

I went to the University, I stood out Whilst many of my peers are project and publications dependent on their supervisors, I entirely unaided, invested my skills and experience for project and publications independence; in thus doctoral study I have made 85+ publications, suggested, proposed, and implemented my own thesis proposal

While studding postgraduate, I stood out, discovered and developed Vaccine, immunotherapy, immuno-modulatrory and genome modulatory to cure HIV-1

I went to Ethiopia; while I became post graduate lecturer, I stood out, discovered and designed hardware/Software immune-biotechnology, which is crucial for dead list infectious diseases drug and vaccine development and to decreases 98% animal models and clinical trials errors

While I have been working there as general director, I stood out, developed two feasibility studies for the large scales investment business

While COVID-19 Pandemic world crisis began, I stood out, developed research project—Study on Immuno-modulatory and inhibitory as cure COVI-19 patients with comorbid illness **project on progress**

Thus in many different aspects, I stood out from my peers and I am determined to achieve all my goals**.**

The Meeting Covered:

- Brief Summary
- Immunopathogenesis
- AZEE functions in Alveolar macrophages in COVID-19
- Method of Killing COVID-19
- Benefit of AZEE
- Objectives
- Design Overview
- Endpoints
- Inclusion Criteria
- Exclusion Criteria
- Study Population
- Phase
- Description of Sites/Facilities Enrolling Participants
- Description of Study Intervention
- Study Duration
- Participant Duration
- Potential risk and benefits from AZEE
- Justification for dose chosen
- Schema: Diagram #1 Flow diagram (randomized controlled trial)
- Diagram #2 Process diagram (randomized controlled trial)
- Diagram #3 Timeline diagram (randomized controlled trial)
- Schhedule Activities(SOA): The schedule below is provided study activities
- Implementation Considerations for site
- Diagram: Site assessment
- Study budget

Project Title

Phase IIb/III Studies of Immuno-modulatory and Inhibitory (AZEE) in the COVID-19 with Co- morbid illness Patients

Protocol Number: 03
Principal Investigator: Zelalem Kiros Bitsue Ph.D.

Sponsor:
US-AHO

Collaborator:
???

Information provided by (Responsible Party):
Dr. Zelalem Kiros Bitsue, PhD. Immunologist,

Brief Summary

This IIb / III clinical trial program focuses on the COVID-19 with Co- morbidity illness in order to start a better development of combination therapy of (AZEE):

Determine the Disease control rate (DCR of phase IIb/III of combination of (AZEE) in the COVID-19 with Co- morbidity illness Patients.

Condition or disease	Intervention/treatment	Phase
COVID-19 with Co-morbidity illness Patients.	Drug/Injections/Inhalation: Combination Therapy (AZEE),of COVID-19 with comorbid illness	Phase II Phase III

Phase IIb/III Studies of Immuno-modulatory and Inhibitory AZEE in the COVID-19 with Co- morbid illness Patients

The ImmunoPathogenesis Factor and Mechanisms of COVID-19

- COVID-19 antigen one of the reason high production of the reactive oxygen species, which result lung lesions, and bleeding;
- COVID-19 antigen the cause of chronic infection, results defect of alveolar macrophages, reduced phagocytosis activity releases auto antigen to auto reactive T cells results autoantibodies and autoimmunity;
- Moreover, up regulate Dendritic cells, macrophages pheno type M2, releases cytokines and Growth factors results defects of NK cells, NKT cells, and Neutrophils, results reduced killing of COVID-19 antigen in lung by NK Cells, MQ and Neutrophils, reduced DCs presenting auto antigens, reduced secretion of regulatory cytokine by NK T cells, reduced phagocytosis activity results organ damage or cancer.

Alveolar Macrophage Maintaining Pulmonary Homeostasis

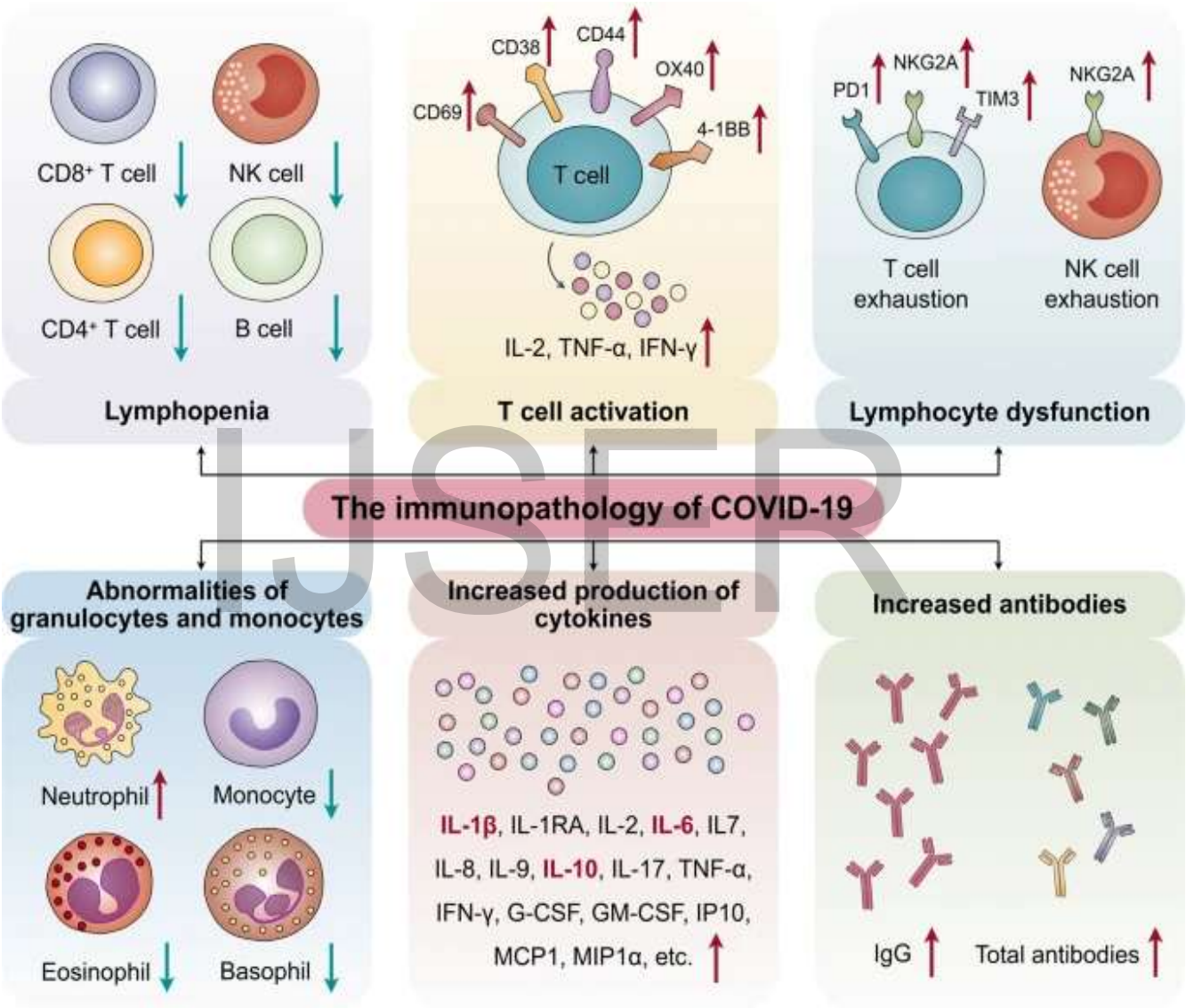
- Surfactant Degradation
- Removal of cellular Debris
- ✓ Efforocytosis
- Host Defense
- Immune surveillance
- Resolution of Inflammation
- Tissues repair

Alveolar macrophages dysfunction in COVID-19

- Increased cytokine production (TNF-α, IL-1β, IL-6, IL-8);
- Increased reactive oxygen species;
- Decreased IL-10;
- Defective Phagocytosis;
- Defective Efferocytosis (Efferocytosis triggers specific downstream intracellular signal transduction pathways, for example resulting in anti-inflammatory, anti-protease and growth-promoting effects. Conversely, impaired efferocytosis has been linked to autoimmune disease and tissue damage)

Phase IIb/III Studies of Immuno-modulatory and Inhibitory AZEE in the COVID-19 with Co- morbid illness Patients

Understanding the basics of COVID-19 immunopathogenesis

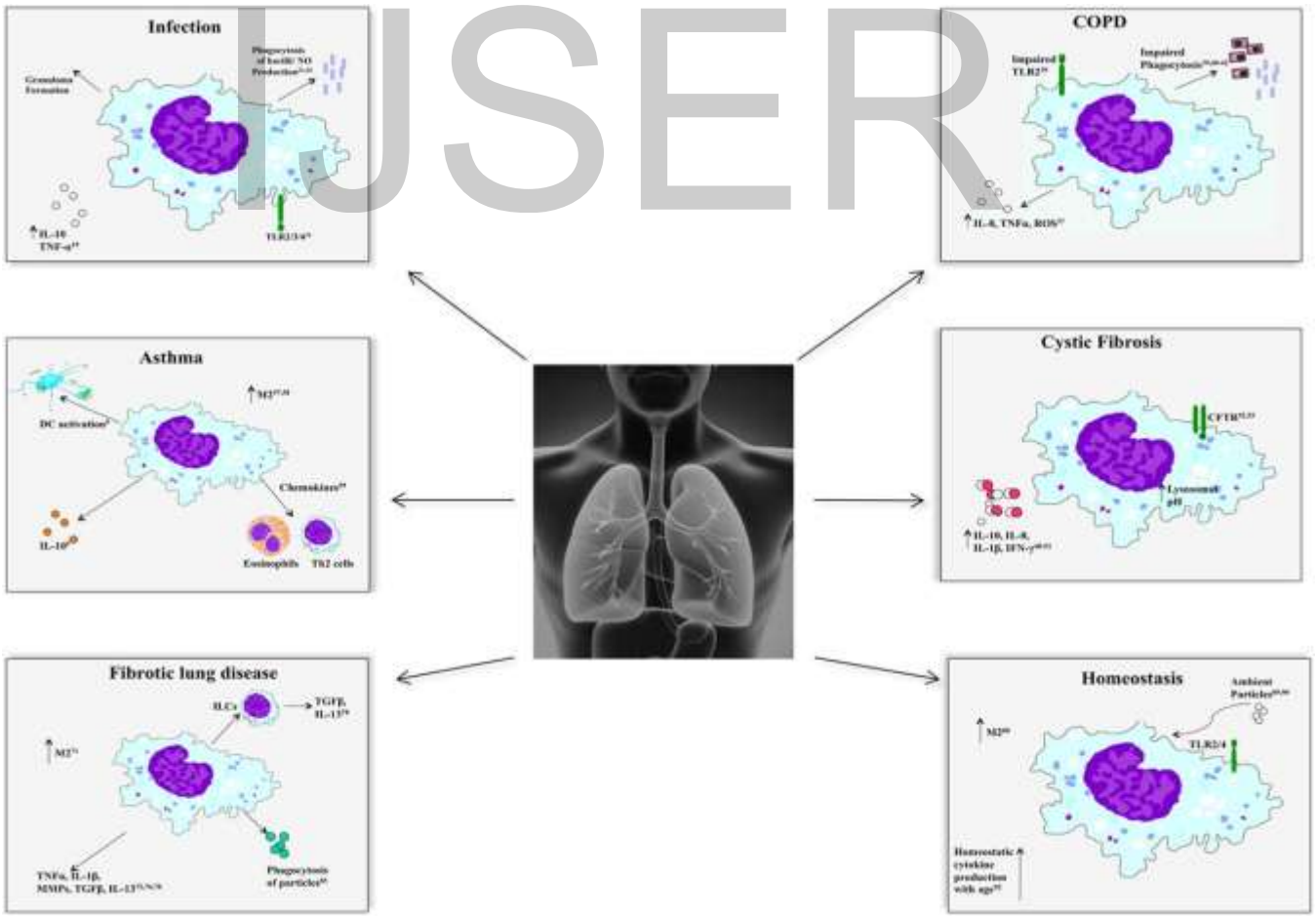


Phase IIb/III Studies of Immuno-modulatory and Inhibitory AZEE in the COVID-19 with Co- morbid illness Patients

AZEE functions in Alveolar macrophages in COVID-19

- Restore Alveolar macrophages dysfunction;
- Decreased cytokine production (TNF-α, IL-1β, IL-6, IL-8);
- Decreased reactive oxygen species;
- Increased IL-10;
- Activate Alveolar macrophages Phagocytic activity;
- No complication or tissue damage

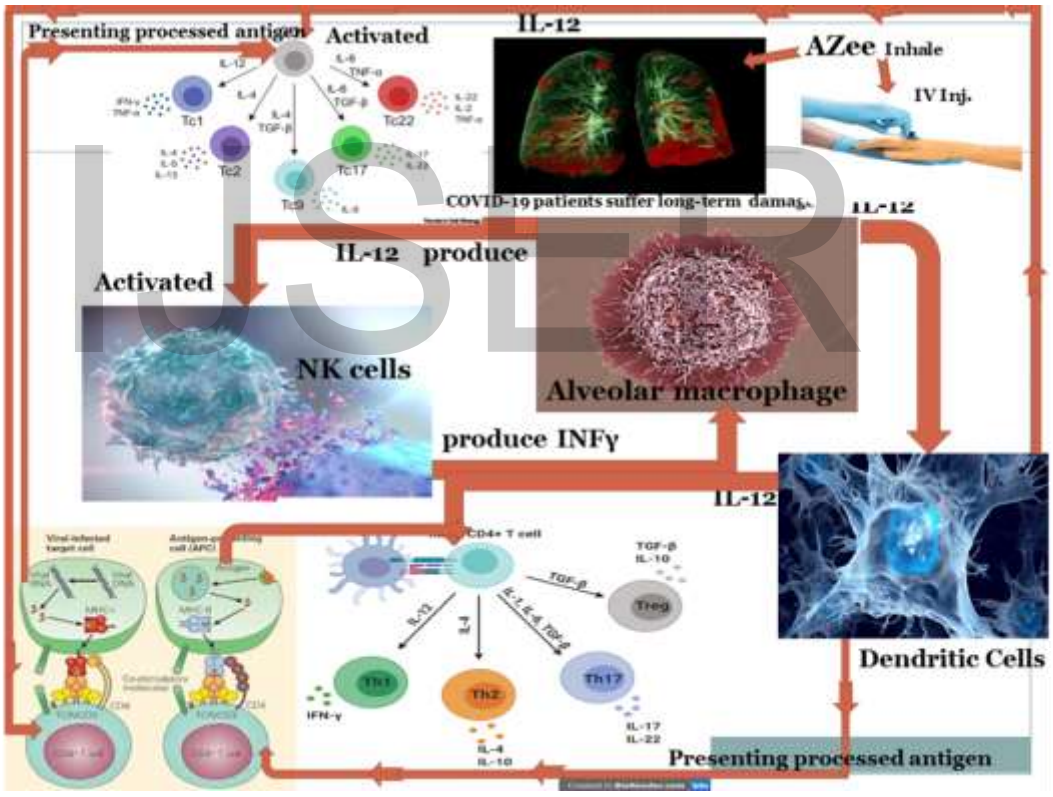
Why I focused on Lung Macrophage?
Pulmonary macrophages play a central role in lung disease. The plastic nature of pulmonary macrophages, combined with their strategic positioning at the interface of the airways and the environment, results in complex contributions to diseases of the airways



Phase IIb/III Studies of Immuno-modulatory and Inhibitory AZEE in the COVID-19 with Co- morbid illness Patients

Method of Killing COVID-19

- Opsonization (Enhance the phagocytic activity);
- Antibody Dependent cell mediated Cytotoxicity (ADCC)" (lysis infected cells);
- Balance modification;
- Restoration of Immune cell dysfunction;
- Signaling using Paracrine , mutual activation methods



The following diagram is drawn by Dr. Zelalem Kiros Bitsue PhD Immunologist and Original

Fig shows Method of Killing COVID-19, restoring immune cells and developing Antibodies against COVID-19

Phase IIb/III Studies of Immuno-modulatory and Inhibitory AZEE in the COVID-19 with Co- morbid illness Patients

Benefit of AZEE

- Save the life of people;
- Help to recover Economy crisis around globe;
- Reignite the social affairs;
- Make world back to the normal activity and life;
- Most of all the patients once they get this treatment they will develop antibodies against COVID-19

Objectives

Primary Objective:

- To determine the the effeicancy rate of combination therapy (AZEE) as COVID -19 Cure in Human

Secondary Objectives:

- To determine the level of IFN-γ, IL-6, IL-1β, IL-10, IL-12, IL-4, IL-17, TGFβ, IgG, IgM, IgA;(ELIZA);
- To determine the gene expression of Tbet, RORγt, FOXP3, IFN γ, STAT-3, SOCS, STAT-5,IL17, IL-4, IL-10, IL-1β, TNFα, IL12, IL-6, IFN-γ, and HPRT1;(RT-PCR);
- To determine the Lymphocyte Subsets (FITC anti-human CD4 Antibody, APC anti-human IFNγ Antibody, PE anti human CD8a Antibody, APC anti-human IL-17a Antibody, APC anti—human CD3 Antibody;(FCM);
- To monitor daily for signs of clinical disease and severity of disease

Design Overview

- Randomized, placebo-controlled trial master protocol to evaluate the safety and efficacy of Immuno-modulatory and Inhibitory against COVID-19 for the treatment of adult patients with COVID-19 with comorbid illness who are hospitalized;

- This Phase IIb platform design, safety will be evaluated and two intermediate outcomes will be assessed to determine whether an agent advances to phase III;

- Estimated sample size of 1000 (100 in each group) for each study agent;

- Participants can be randomized: to a single (it can be more, depending on the study drug) infusion of AZEE or placebo;
- No restriction on Lasix and aspirin will be provided to all patients

Phase IIb/III Studies of Immuno-modulatory and Inhibitory AZEE in the COVID-19 with Co- morbid illness Patients

Endpoints

Primary endpoints:

- Stage 1: 7-ordinal outcome scale of pulmonary and extra-pulmonary disease progression, and or 13 basic Complications or death at Day 5;
- Stage 2: sustained recovery defined as 7 consecutive days at pre-COVID home;
- All participants in Stage 2 (which includes people who were enrolled in Stage 1) will be followed for 90 days in total.

Secondary Endpoints

Phase III clinical trial:

- To see therapeutic outcomes among demographic group, and geographic location of COVID-19 Positive with (ICU, Ward, with any co-morbid illness);
- Describe the clinical trial design, based on available safety data for the therapeutic agent;
- Define the patient selection strategy;
- Justify the number of patients chosen for the Phase III trial (based on the proposed outcome measures and the appropriateness of the statistical methods);
- Justify the sample size and duration of the Phase III clinical trial for the specific disease population;
- Provide assurance that the proposed study can be completed within its budget and within the time limits.

Inclusion Criteria

Stage 1 Inclusion criteria:

- Adults aged ≥18 years; hospitalized; COVID-19 symptoms ≤12 days; with extrapulmonary complications i.e. stroke, meningitis, encephalitis, myelitis, myocardial ischemia, myocarditis, pericarditis, symptomatic congestive heart failure, arterial or deep venous thrombosis or pulmonary embolism

Or

- The following pulmonary criteria i.e. current or imminent requirement for any of the following: invasive mechanical ventilation, ECMO, mechanical circulatory support, vasopressor therapy, new renal replacement therapy at this admission

Or

- 13 Basic Complications Coronavirus

Acute Respiratory Failure, Pneumonia, Acute Respiratory Distress Syndrome (ARDS), Acute Liver Injury, Acute Cardiac Injury, Secondary Infection, Acute Kidney Injury, Septic Shock, Disseminated Intravascular Coagulation, Blood Clots, Multisystem Inflammatory Syndrome in Children, Chronic Fatigue and Rhabdomyolysis

Inclusion Criteria

Stage 2 inclusion criteria

- Adults aged ≥18 years; hospitalized for acute care for clinical manifestations of COVID-19;
- COVID-19 symptoms ≤12 days; COVID-19 PCR +ve within 3 days of randomization (or PCR ≥3 days prior to randomization PLUS symptoms/signs suggestive of progressive COVID-19)

Exclusion Criteria

- Patients with brain metastases;
- Patients with bone metastases;
- Patients who have primary immunodeficiency;
- Organ transplants recipients;
- Patients who have received the therapy of chemotherapy within 4 weeks or radical radiotherapy within 6 weeks before enrollment;
- Pregnant or breast-feeding women, or patients (male and female) who have pregnancy plan;

Exclusion Criteria

- Patients who had received a therapy of another investigational drug within 1 month;
- Known active hepatitis B/hepatitis C, positive HIV/ syphilis antibody;
- Patients who have received therapy of major surgery within 6 weeks or biopsy surgery within 2 weeks before enrollment;
- Patient who need long term treatment of cortical hormone or other immunosuppressive drugs such as visceral organ transplanters;
- History of drug abuse;
- Other patients judged ineligible for enrollment in the study by the investigator (sub-investigator).

Study Population

- Specify the sample size 1000 participants b/se 900 of them for 9 groups and 100 extra participants will the replacement of any participants died, or discontinues from the group;
- Group 8 is a healthy group with a prophylaxis (for stimulation of immune cells);
- Group 9 is a control group without any combination therapy and *hormones but Placebo(N. Saline);*
- *Gender both male and female, age group >18years, general health status: COVID-19 with co-morbid illness, and COVID-9 without co-morbid illness, and health group;*
- *Geographical location will be Africa Region;*
- *Phase Phase IIb/III, drugs*

Description of Sites/Facilities Enrolling Participants

- Total No. of Participants 1000 Human;
- No. of Study site: 01;
- Duration of the Study: 3 months;
- Type of the Study interventional and genetic, the study will be Randomized, Single blinded, and using blood samples;
- Since COVID-19 Pandemic based on consent and recommendation of sponsors the study will be done in other geographic location, however, tentative choice of study in the African Region

Phase IIb/III Studies of Immuno-modulatory and Inhibitory AZEE in the COVID-19 with Co- morbid illness Patients

Description of Study Intervention

- Intervention studies often test the efficacy of drugs;
- Controlled clinical trials in which individual subjects are assigned to the competing interventions;
- provides clinical trials with a powerful advantage over observational studies;
- provided the assignment to a treatment group is done randomly with a sufficiently large sample size;
- Provide the best opportunity to control for confounding and avoid certain biases.

- The dose is varied based on weight and age(old, young, children, infant);
- Sex both male and Female;
- Disease condition(Hyperbaton, Diabetic, Acute Respiratory Failure, Pneumonia, Acute Respiratory Distress Syndrome (ARDS), Acute Liver Injury, Acute Cardiac Injury, Secondary Infection, Acute Kidney Injury, Septic Shock, Disseminated Intravascular Coagulation, Blood Clots, Multisystem Inflammatory Syndrome in Children, Chronic Fatigue and Rhabdomyolysis...);
- The route will be Intravenous, Oral and Inhalation

Study Duration

Estimated time 3 months, from Noember, 2020 to April, 2021

Participant Duration

Time (3 months) it will take for each individual participant to complete all participant visits.

Potential risk and benefits from AZEE

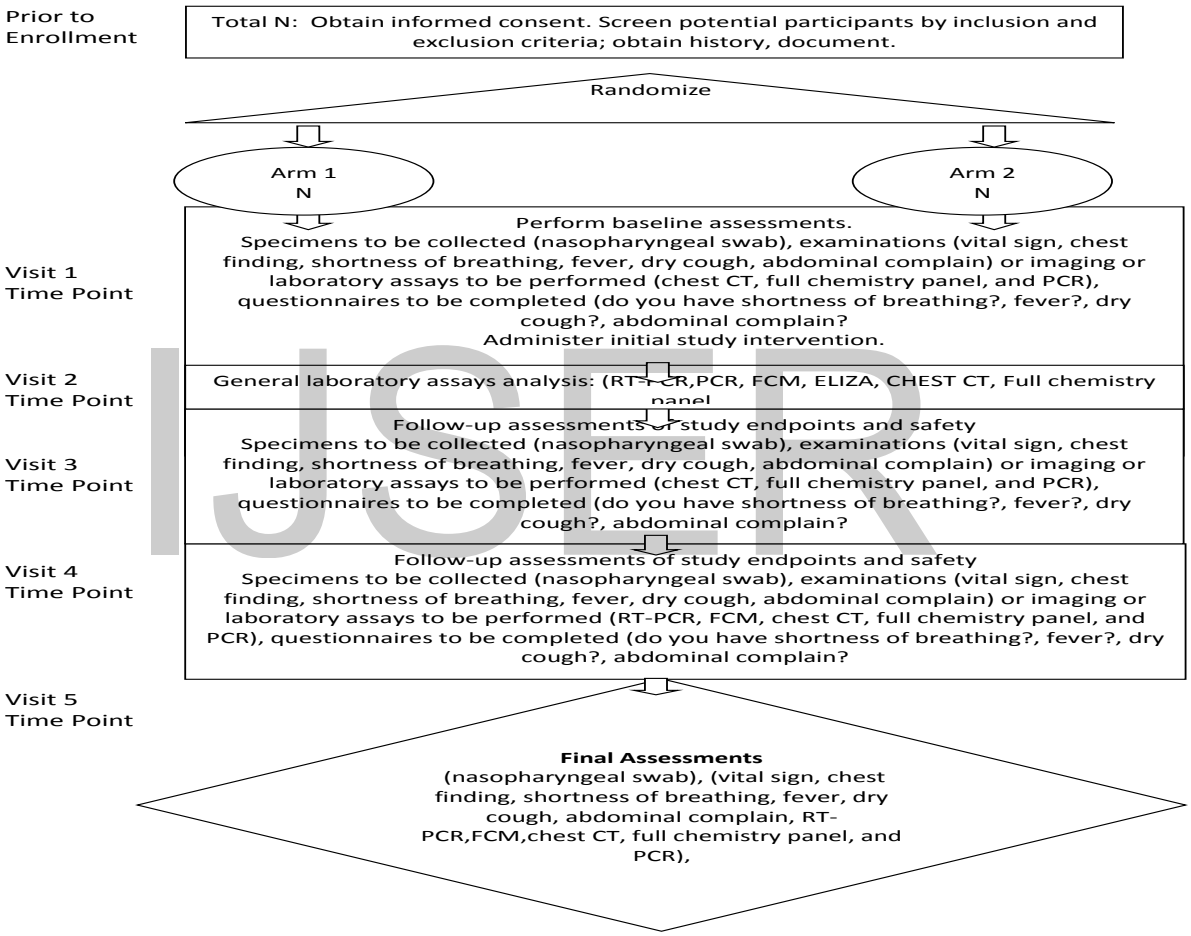
- Potential risks for injection of **AZEE** directed toward a microbial pathogen are mostly associated with either injection-related immediate and non-immediate hypersensitivity reactions. Anticipated risk is considered low;
- AZEE is a highly specific Immuno-modulatory and inhibitory directed at human immune cells, lymphocytes, such us B cells receptors (IgM, IgG), APCs (MQ, DC, NK Cells, NKT Cells, Gilial, Neutrophils, CD4 T Cells (Th1,Th2, Treg), CD8 T Cells, genes transcription and expression and enzymes;
- AZEE entirely involved in cells Proliferation, differentiations, dysfunction restoration, activation, viral replication inhibition, modulation and killing of antigen as well as strongest scavengers;
- AZEE at high dose of inhalation may cause lung cancer, auto reactive immune cells.
- AZEE will be administered to patients at sufficiently high dose of Injection levels to maintain tolerance in the entire immune cells and restore immune dysfunction, inhance immune cells ability, and inhibitory in severe and acute viral disease states;
- At low dose Inhalation kills SARS-CoV-2 and activate the phagocytic activity of lung macrophages in the Alveolar and activate the humeral immune responses;
- I have already well furnished Protocol and provided sufficient safety data Non-Clinical Safety Studies and Clinical Safety Studies, previously conducted on relevant species and Human, that's adequate to characterized potential adverse effects, Pharmacodynamics, Pharmacokinetics, Pharmacology /Toxicology, Clinical Pharmacology, and several published literatures for descriptive to support the and initiate Clinical Trials.
- On June 2020, I (US-AHO) requested US- Food and Drug Administration (FDA) for recommendation for US-AHO new specific combination therapy as COVID-19 Cure, and US-FDA recommended initiating clinical trials, on Sun, Aug 9, 8:27 AM.

Justification for dose chosen

- AZEE the dosing varied in mg IV irrespective of body weight per day for 10days to 3 weeks;
- The projected human half-life is expected to be in the 4hour - 4 weeks range;
- The injectable significantly at high dose at starting varied in mg IV and after 5 days moderate dose for the remaining dose and inhalation at low dose remain the same dose, in Study AZEE is expected to have a sustained concentration level for at least 30 days;
- AZEE is provided in vials of ml solution containing varied in mg each;
- Must be stored between 2ºC and 8ºC;
- Each of them a total of 20 **vials** is required for dosing of the agent at varied mg dosage;
- Placebo is N-saline;
- The study medication is prepared by un-blinded pharmacist at the local pharmacy;
- To ensure blinding of the participant and clinical staff a colored sleeve will be placed over the infusion bags used;
- Injection should be started within 4 hours after the infusion has been prepared by the pharmacist well skilled research nurse.

SCHEMA

Diagram #1 Flow diagram *(randomized controlled trial)*



Phase IIb/III Studies of Immuno-modulatory and Inhibitory AZEE in the COVID-19 with Co- morbid illness Patients

Diagram #2 Process diagram (randomized controlled trial)

Week 1 (1 Sep, -7 Sep,2020) Screening

- Total n=1000
- Obtain informed consent 1000
- Screen potential participants by inclusion and exclusion criteria 1000
- Obtain history, document 1000

Week 2 (8 Oct, - 29 Oct,2020) Randomization

- Intervention Group 1-9 (n=100)
- Placebo (n=100)
- Control (n=100

Week 6 (1 Nov - 7 Nov, 2020) Follow-up assessments of study endpoints and safety
Baseline assessments/ Study Intervention

- Specimens to be collected (nasopharyngeal swab, blood), examinations (vital sign, chest finding, shortness of breathing, fever, dry cough, abdominal complain) or imaging or laboratory assays to be performed (chest CT, EKG, full chemistry panel, and PCR), questionnaires to be completed (do you have shortness of breathing?, fever?, dry cough?, abdominal complain? Administer initial dose of study intervention

Week 7 (8 Nov, - 15 Nov 2020)

- General laboratory assays analysis: (RT-PCR,PCR, FCM, ELIZA, CHEST CT, EKG, Full chemistry panel, western blot)

Week 9 (28 Nov - 5 Dec, 2020) Follow-up assessments of study endpoints and safety

- Specimens to be collected (nasopharyngeal swab,blood), examinations (vital sign, chest finding, shortness of breathing, fever, dry cough, abdominal complain) or imaging or laboratory assays to be performed (chest CT, EKG, full chemistry panel, and PCR), questionnaires to be completed (do you have shortness of breathing?, [illegible]al complain?

Week 13 (6 Dec - 13 Dec, 2020) End of Study Assessments

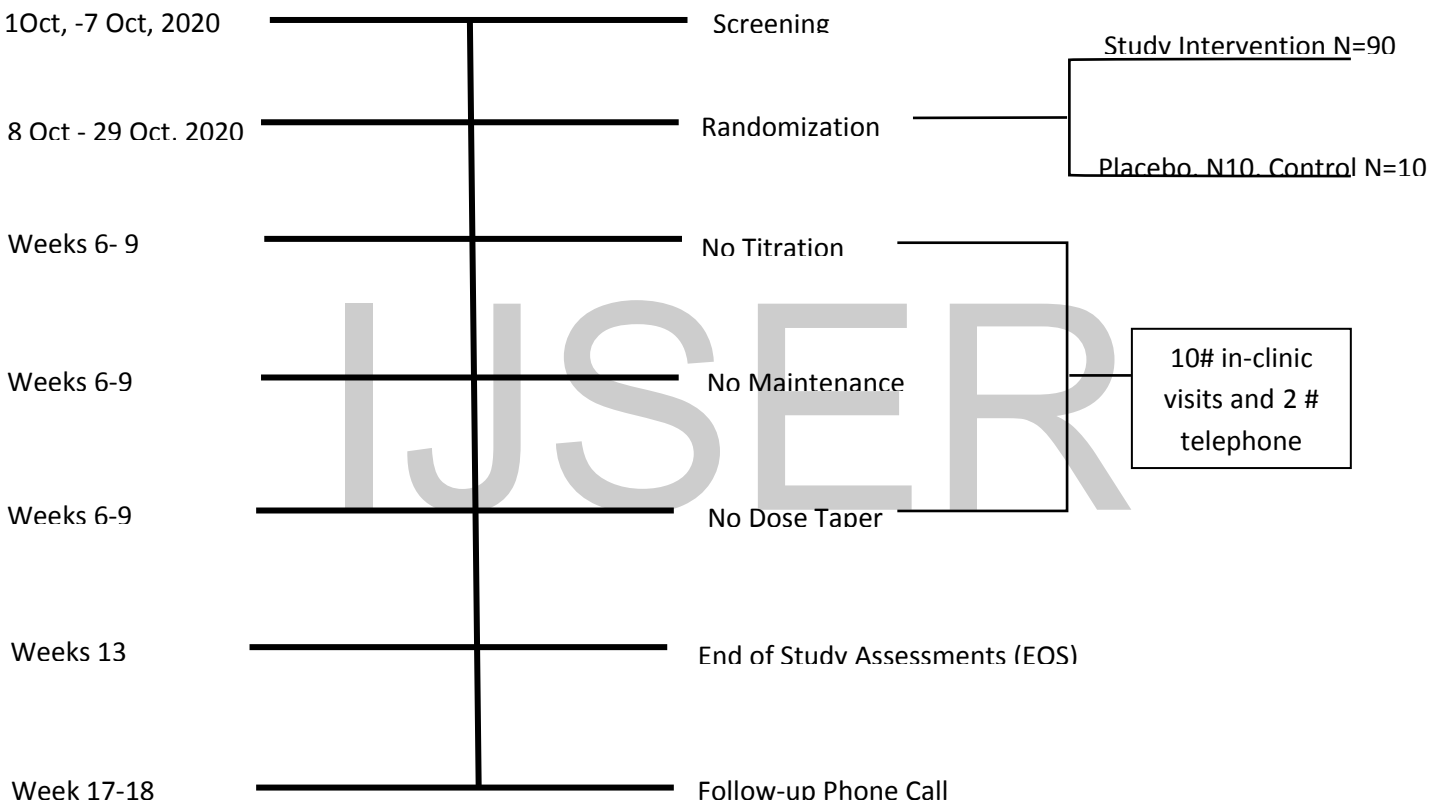
- Specimens to be collected (nasopharyngeal swab, blood), examinations (vital sign, chest finding, shortness of breathing, fever, dry cough, abdominal complain), questionnaires to be completed (do you have shortness of breathing?, fever?, dry cough?, abdominal complain?, General laboratory assays analysis: (RT-PCR,PCR, FCM, [illegible]try panel, western blot

Week 17 / (14 Dec-21 Dec 2020) Follow-up Telephone Call

- questionnaires to be completed (do you have shortness of breathing?, fever?, dry cough?, abdominal complain?,

Phase IIb/III Studies of Immuno-modulatory and Inhibitory AZEE in the COVID-19 with Co- morbid illness Patients

Diagram #3 Timeline diagram (randomized controlled trial)



Phase IIb/III Studies of Immuno-modulatory and Inhibitory AZEE in the COVID-19 with Co- morbid illness Patients

SCHEDULE OF ACTIVITIES (SOA)

The schedule below is provided study activities

Procedures	Screening Day 1 -Day 7	Enrollment/Baseline Visit 1, Day 8	Study Visit 2 Day 9	Study Visit 3 Day 10	Study Visit 4 Day 11	Study Visit 5 Day 12	Study Visit 6 Day 13 +/-29 day	Study Visit 7 Day 30 +/- 37 day	Study Visit 8 Day 44 +/- 51 day	Study Visit 9 Day 65 +/-90 day	Final Study Visit Day 100 +/-1 07 day	Follow up Visit 11 Day 135 +/- 142 day	Study Visit 12 Day 143 +/-158 day
Informed consent	X												
Demographics	X												
Medical history	X												
Randomization	X												
Administer study intervention		X	□	□	X	□	□						
Concomitant medication review	X	X----------X											
Physical exam (including height and weight)	X						X		X	X			
Vital signs	X						X		X	X			
Height	X						X		X	X			
Weight	X						X		X	X			
Performance status	X						X		X	X			
Hematology	X						X		X	X			
serum chemistry [a]	X						X		X	X			
Pregnancy test [b]	X												
EKG (as indicated)	X						X		X	X			
Adverse event review and evaluation	X	X----------X											
Radiologic/Imaging assessment	X						X		X	X			
Other assessments (immunology assays, pharmacokinetic)	X						X		X	X			
Complete Case Report Forms (CRFs)	X	X	X	X	X	X	X	X	X	X			

A: Albumin, alkaline phosphatase, total bilirubin, bicarbonate, BUN, calcium, chloride, creatinine, glucose, LDH, phosphorus, potassium, total protein, AST, ALT, sodium.
B: Serum pregnancy test (women of childbearing potential).
C. RT-PCR,PCR,FCM,ELIA,CALTURE,

Phase IIb/III Studies of Immuno-modulatory and Inhibitory AZEE in the COVID-19 with Co- morbid illness Patients

Implementation Considerations for site

- Baseline examination, randomization, and infusion can be given in hospital;
- Assessments at days 0, 1, 3, 5, 14, 28, 60 and 90 includes PK;
- Infusion pump for administration of study Investigational Medicinal Product (IMP) (single IV infusion over XX hrs) and inhalation once per week for max 3 weeks while hospitalized;
- MUST have resuscitation equipment available, including adrenaline, antihistamines, antipyretics, defibrillator etc;
-
- Medical records are required for disease progression or death;
- Blood draws for safety and for central specimen storage on day 0, 4, 14, 28 and 90 (- 70-80^{o}C freezers). Immunological analysis machines and equipment (RT-PCR, PCR, FCM, ELIZA, CHEST CT, Full chemistry panel, western blot, Ultrasound,..)

Pharmacy

Option for shared pharmacy that can serve several sites in the same city

- Computer access in the pharmacy, the un-blinded Pharmacist of the record will be required to do the randomization
- AZSCC stored at required temperature – COLD CHAIN 2-8^{o}C, with temperature monitoring and backup generator if power outage, and/or urgent alert with study drug movable to alternate fridges and is made up with water for injections, and into a 100mL bag of N-saline for IV infusion
- N-saline provide locally
- Study IMP/placebo infusion masked with provided covers, to avoid any un-blinding
- Inhalation is kept at 2-8^{o}C

Regulatory approvals

- Rapid translation facilities, if translation is needed;
- Urgent ethics and regulatory approval pathways for COVID-19 research;
- Rapid importation and distribution of study Investigational Medicinal Product (IMPs)

Phase IIb/III Studies of Immuno-modulatory and Inhibitory AZEE in the COVID-19 with Co- morbid illness Patients

Timelines and enrollment

- Begins in December – January 2020, dependent on availability of study product;
- Staggered start of sites;
- Study completed in 18 Months dependent on COVID activity;
- Likely 7-8 IMPS will be tested during this time;
- Enrollment per site: ideally at least 900+ participants;
- Sites will open and close to enrollment depending on activity

Implementation in your setting

Site assessment

\

Site Name

INSIGHT Number if has one

Completed by:

Date:

Does your site have a current Federal Wide Assurance (FWA) and plan to maintain it?

☐ No (not eligible-stop here)

☐ Yes, FWA#_____ Date of Expiration_____

If yes, please respond to the following:

Estimate the total number your site will enroll this year _____

REC and/or regulatory requirement	Time to obtain
Translation	
Ethics approvals	
Regulatory	
Importation permits	
Contract sign off	
Other:	

Participant recruitment	response
How would you approach the recruitment of patients into the study?	
Are patients admitted to hospital for just quarantine in your setting?	
Can AZSCC be administered IV in your inpatient care setting?	
Do you have any experience in passive immunotherapy trials with hIVIG, IV Injection, plasma infusions?	
Do you have resuscitation equipment available, and staff trained in its use?	
Is there out of hours cover for research trials?	
Can you recruit 7 days a week?	

Laboratory requirement	response
Do you have safety lab facilities?	
Do you have labs that can process and store the storage samples at -70/-80oC?	
Is there any difficulty in sending storage samples to the USA?	
Would you be able to participate in a human genomics sub-study – with additional (and optional) consent, and a single blood draw?	
Can human genomics samples be sent to the Lab for analysis?	

Research & Related Budget

H. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (F + G)	2,203,300.00
I. Fund Requested	Funds Requested ($)*
Total Fund Requested	2,500,000.00

Time for Question
???

THANK YOU FOR YOUR ATTENTION

Stay Safe