EB-P12-01 Directed Energy Program

A Randomized, Placebo Controlled, Double Blind Study to Evaluate the Safety and Antiviral Activity of the EmitBio Device in SARS-CoV-2 Infected Individuals with Uncomplicated COVID-19

NCT04662671

About The Study

- The sponsor, EmitBio Inc., conducted the study in collaboration with a third party CRO who has conducted over 200 clinical trials of investigational treatments in adherence to good clinical practices (GCP) for programs that have led to >50 FDA approvals.
- The study aimed to evaluate the safety and efficacy of an investigational device alone without additional pharmaceutical intervention in subjects with mild to moderate COVID-19.
- 31 participants were enrolled in the first cohort of this study conducted at two sities in the U.S.
- Additional information about the study can be found here on ClinicalTrials.gov (NCT04662671).

Trial Design

- The study was a placebo controlled, randomized, double-blind study, meaning that everyone, including the sponsor, the investigator conducting the trial, and the subject did not know which treatment device (active vs. inactive) they were being treated with.
- The study aimed to determine product safety and the treatment difference between a 4-day, twice daily dosing regimen of either the investigational device emitting safe electromagnetic energy or the placebo device (inactive but identical in user experience), randomized in a 2:1 ratio.
- Outcome measures included reduction of SARS-CoV-2 viral load and assessments of clinical signs and symptoms consistent with COVID-19 in an outpatient setting including:
  - Time weighted average change in viral load by RT-qPCR
  - Mean change in viral load at each visit by RT-qPCR
  - Time to alleviations of signs and symptoms
- Safety, tolerability, and efficacy assessments were assessed at study visit days 1, 3, 5, and 8.

Inclusion Criteria (Abbreviated)

To participate, subjects had to meet certain eligibility requirements including:

- Male or non-pregnant female subjects, 18 to 65 years of age.
- Positive test for SARS-CoV-2 antigen via nasal swab at or within the past 24 hours of the screening visit detected using an FDA authorized SARS-CoV-2 antigen test.
- Onset of signs and symptoms of COVID-19 no longer than within the past 3 days.
- Entry criteria require subjects to have either:
  a) a fever of at least 100°F, or
  b) at least two moderate or severe symptoms (cough, sore throat, nasal congestion, headache, chills/sweats, muscle or joint pain, fatigue, and nausea) at the time of screening.

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Exclusion Criteria
(Abbreviated)

- Subjects with a BMI ≥ 36
- COVID-19 signs and symptoms indicative of acute respiratory distress or imminent serious medical outcomes. Potential study subjects presenting with any of the following more severe lower respiratory, cardiac or neurological signs associated with COVID-19 were to be referred for immediate medical care and were not eligible for the study:
  - Fever > 104° F
  - Cough with sputum production
  - Rales and/or rhonchi
  - Difficulty breathing or respiratory distress defined by a respiratory rate ≥30 per minute, heart rate ≥125 per minute, SpO2 ≤93% on room air at sea level or PaO2/FiO2 <300.
  - Persistent pain or pressure in the chest
  - Confusion

Study Team

Terry Jones, M.D.
Medical Director of J&S Studies and Principal Investigator (College Station, TX)

Jorge Santander, M.D.
APF Research, Investigator (Miami, FL)

John McNeil, M.D., Ph.D.
Chief Medical Officer of EmitBio, Medical Monitor and Safety Monitoring Committee Chairman (Durham, NC)

For additional information on this trial, please contact us via info@emitbio.com.

Results

- Baseline SARS-CoV-2 viral load ranged from 10^2 to 10^8 mRNA copies/mL across 28 of 31 subjects confirmed positive via saliva RT-qPCR after randomization. Treated subjects (N=20) experienced a 99.9% mean reduction of SARS-CoV-2 viral load in saliva between the baseline visit on Day 1 and Day 8. Subjects receiving placebo (N=11) saw virtually no change from baseline according to a comparison of arithmetic means.
- The median time to alleviation of patient reported signs and symptoms, as measured by the time when all eight symptoms had been assessed by the subject as none (0) or mild (1), and no single symptom reoccurs at a level above mild (1), demonstrated a clinically meaningful accelerated time to symptom resolution when treated by the active device of over 48 hours compared to the control group.
- No treatment related or serious adverse events were observed for any subjects.

About EmitBio

EmitBio Inc. is a life science company using the precise delivery of light to stimulate, heal, and protect the body. EmitBio™ is comprised of a superior team of internationally recognized light science specialists merged with immunology and virology life science experts, prepared to react quickly to the pandemic and rapidly scale manufacturing for lifesaving medical breakthroughs. EmitBio is currently using advanced LED technology to create light that is fundamental to human health, harnessed for healing and for bodily defense. For more information, visit www.emitbio.com.

EmitBio Inc. is headquartered in Durham NC and is an operating subsidiary of KNOW Bio LLC.

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