TrialSiteNews

Is there a Problem with the Lopez-Medina, Colombia-based Study Implicating Ivermectin? Major Pharma Companies Including Merck Funding the Trial Site during the Study

doctrumpet
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5 Comments

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Although a great majority of ivermectin-based studies have indicated real promise, one particular study conducted by a small trial site in Colombia received unprecedented media attention when the study results indicated negligible impact. What hasn't been disclosed by media is the seriously questionable pharmaceutical industry support of this one trial site. During the study, a handful of some of the largest drug companies in the world gave this site money. What's not clear is why this occurred and whether the funds are correlated to some nefarious agenda. This author suggests that the publisher should have scrutinized this industry funding perhaps more carefully.

On March 4th, 2021, an article appeared in *JAMA* titled, "Effect of Ivermectin On Time To Resolution of Symptoms Among Adults With Mild COVID." It concluded, "The findings do not support the use of ivermectin for treatment of mild COVID-19, although larger trials may be

Dr. Eduardo Lopez-Medina et al. from Cali, Colombia, randomized 400 mildly ill patients, averaging 37 years old, to ivermectin 0.2 mg/kg or placebo. The time to resolution for ivermectin-treated patients was 10 days and placebo patients 12 days, which was not statistically significant.

Much has been written about the methodologic problems of the study but few read to the bottom of the article to see this:

Conflict of Interest Disclosures: Dr. López-Medina reported receiving grants from Sanofi Pasteur, GlaxoSmithKline, and Janssen as well as personal fees from Sanofi Pasteur during the conduct of the study. Dr. Oñate reported receiving grants from Janssen and personal fees from Merck Sharp & Dohme and Gilead outside the submitted work. Dr. Torres reported receiving nonfinancial support from Tecnoquímicas unrelated to this project during the conduct of the study. No other disclosures were reported.

Considerable press outlets noted this study, we suspect due to the fact that the ivermectin results were negligible, but none of the media addressed the possibility of conflict with industry.

Absolutely nothing has been written about the fact that the study was sponsored by Centro de Estudios en Infectogía Pediatrica and the authors were paid by 3 drug companies making COVID vaccines–Sanofi Pasteur, GlaxoSmithKline, and Janssen– and two making COVID therapeutics– Gilead and Merck.

We have some questions about this. Why did the authors disclose that they were receiving industry sponsor funds during the conduct of the study? Were these funds to actually direct the ivermectin study? That would most certainly be a conflict of interest material.

Merck's expressed their intent on competing against the ivermectin generic approach. Why would this company be funding this small trial site operation in Colombia?

How could *JAMA* even think about publishing an article sponsored by 5 drug companies centering on a study targeting a generic competitor? Any layperson seeing this could think that this was highly suspect.

The potential conflict of interest was so severe that no journal should have published it.

Was there a pressing need to know if 37-year-old patients got better sooner with ivermectin than placebo? There were a lot of resources put into this study. The only possible reason to do the study was for drug companies to have a vehicle to publish negative data about ivermectin. Is there anyone who believes the study was sponsored to add to the scientific knowledge about ivermectin for the treatment of COVID?

On February 4th, 2021, Merck, who had the original patent on ivermectin, put out a statement regarding ivermectin for COVID:

• No scientific basis for a potential therapeutic effect against COVID-19 from pre-clinical studies;

• No meaningful evidence for clinical activity or clinical efficacy in patients with COVID-19 disease; and

• A concerning lack of safety data in the majority of studies.

If Merck believed these statements to be true, why would they feel the need to go public with them?

Merck's vaccine had failed. Merck had bought a company, Oncoimmune, for $425 million and gotten $356 million from HHS in taxpayer money to develop a therapeutic agent, CD24c. They had a material conflict of interest. Later, the European Medicines Agency and World Health Organization both quoted Merck's statement while ignoring the conflict of interest and science in recommending against the use of ivermectin for COVID, other than for research. Were they influenced by Merck? CD24c was dropped, and Merck has oral antiviral molnupiravir in a phase II-III trial. Why would Merck sponsor a trial of ivermectin?

Why would *JAMA* publish an article showing that young patients who are expected to recover quickly don't get better much more quickly with ivermectin?

This article did not warrant publication in *JAMA*. The only possible reason to publish it was to present false, negative information about ivermectin to readers.

ivermectin is ineffective in early COVID. Dr. Adfarsh Bhimraj at Cleveland Clinic who heads the committee writing COVID recommendations for the Infectious Disease Association of America spoke with Helio Medical News on ivermectin. He had a similar observation in the Washington Post.

"This was a well-done, but small trial in patients with mild or moderate disease," Bhimraj said. He suggested that this is a negative study for a non-mortality outcome, but because the numbers were small, it might not have produced a statistically significant difference in effect size. The evidence is not enough to warrant a recommendation for the use of ivermectin. Other US experts who commented on the article have failed to notice the age of the patients and drug company sponsorship. It has crossed few American physicians' minds that *JAMA* could be corrupted and knowingly publish a study with deceptive results in order to help drug companies.

Was the data fraudulent?

If the purpose of the article was to make it appear that ivermectin was ineffective in mild COVID, there is no reason to believe the data was real. There is no published randomized data for comparison. In the Dominican Republic, Dr. Jose Natalio Redondo reported that in 1300 patients with all degrees of illness, the length of illness went from 21 days to 10 days with ivermectin treatment.

Was *JAMA* aware that there was concern they had been corrupted and the article unreliable?

Sixteen members of the AMA Board of Directors were emailed that it appeared that *JAMA* had been infiltrated and the article fraudulent on March 10th, 2021. Eleven *JAMA* editorial board members were emailed about it April 12th. And one was spoken to. The same email was sent to executive editor Dr. Phil Fontanarosa April 13th. This reply was sent:

"Your message was brought to my attention.

their patients? To put things in perspective, Uttar Pradesh, India, with 210 million people, started ivermectin in August. By December, their mortality rate was 0.26 per 100,000. In the US, in December, it was 11 times higher at 2.8 per 100,000. Admissions in Mexico are down 75% due to ivermectin.

The *JAMA* article of 3/4/21 was a cleverly devised drug company creation designed to create the false impression that ivermectin was ineffective in mild COVID by claiming it didn't shorten the duration of illness significantly. They knew people would miss the age of the patients and not read to the bottom of the article to see that it was sponsored by 5 drug company competitors. They knew people would leap to the conclusion that ivermectin was completely ineffective for COVID, not realizing that the article could not address its effects on hospitalization and death. An infectious disease doctor friend sent it to me as proof that ivermectin does not work. Drug companies would not have gone to these lengths if they did not fear ivermectin as a competitor.

JAMA reviewers could not possibly have missed the obvious conflict of interest. It was obviously their intention to spread misinformation. Leaving out the age of the patients was intentional to make readers think it was ineffective in everyone. The article has not only led to patient care being adversely affected but the article has been widely quoted as evidence against the use of ivermectin. WHO says it is the number one article in support of its position.

Doctors should contact *JAMA* to understand what is going on with the investigation. *JAMA* should report on their findings as they committed to this author to undertake an investigation.

Note that views expressed in this opinion article are the writer's personal views and not necessarily those of TrialSite.

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Noninvasive cardiologist involved in treating general cardiology patients. Retired as of 4/1/16. Treated the first reported case of successful use of lipids to treat drug overdose. Published in The Annals of Emergency Medicine. Specialties: Philadelphia area expert in postural orthostatic tachycardia and orthostatic intolerance. Use state of the art medications and surgical referral when appropriate. Newly discovered marked benefit of cranial osteopathy in the diagnosis and treatment.

Responses

June 10, 2021

It is glaringly obvious that the entire world of governments, main stream media, the ultra rich, social media and more are all coordinating in the effort to stifle and control information involving ivermectin effect against covid among many other things. There is much more to all this than just Ivermectin.

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Enzo

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Not only was the JAMA article used by WHO to support their recommendation against ivermectin, but it is also the main reference for European Medicines Agency (EMA) and the french "Agence Nationale de Securité du Médicament" (ANSM) in support of their negative recommendations. In January 2021, ANSM was pressed by means of justice to examine a "RTU" (sort of an emergency approval) for ivermectin. https://blog-gerard.maudrux.fr/2021/01/27/livermectine-au-conseil-detat/ But ANSM took its time and answered "no" on april 1st, after the JAMA article was published, taking it as "the" evience ivermectin in not efficient.

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CoS

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The study design and implementation needs to be thoroughly examined also.

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Adey

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Despite issues on methodology and control in the trial, the age and health status of the participants and possible cross contamination of intervention and control arms, the primary and all secondary measures favoured Ivermectin in numerical terms. What is the likelihood that this could have happened by chance, even if the individual results did not reach statistical significance in what was quite possibly an underpowered study given the uncertainties above?

In any event, I have a question about the analysis of the data. My reading of the paper is that the primary analysis was based on the results for all 200 participants in the intervention arm (Ivermectin) and all 198 participants in the control (placebo) arm.

However, of the 200 in the Ivermectic arm, only 173 (86.5%) received the full 5 day course of Ivermectin. The remaining 27 (13.5%) only received "one or more doses", either because they did not adhere to the prescribed dose (10 (5%)), or because they discontinued due to adverse events (side effects, 17(8.5%)).

This was not meant to be a trial of patients' adherence to treatment protocols, or of their propensity to opt out of treatment in clinical practice, it was supposed to be a trial of the pharmaceutical efficacy of a drug administered in accordance with a pre-defined dosage regime . (only 2 discontinued on medical advice). Surely these 27 who did not

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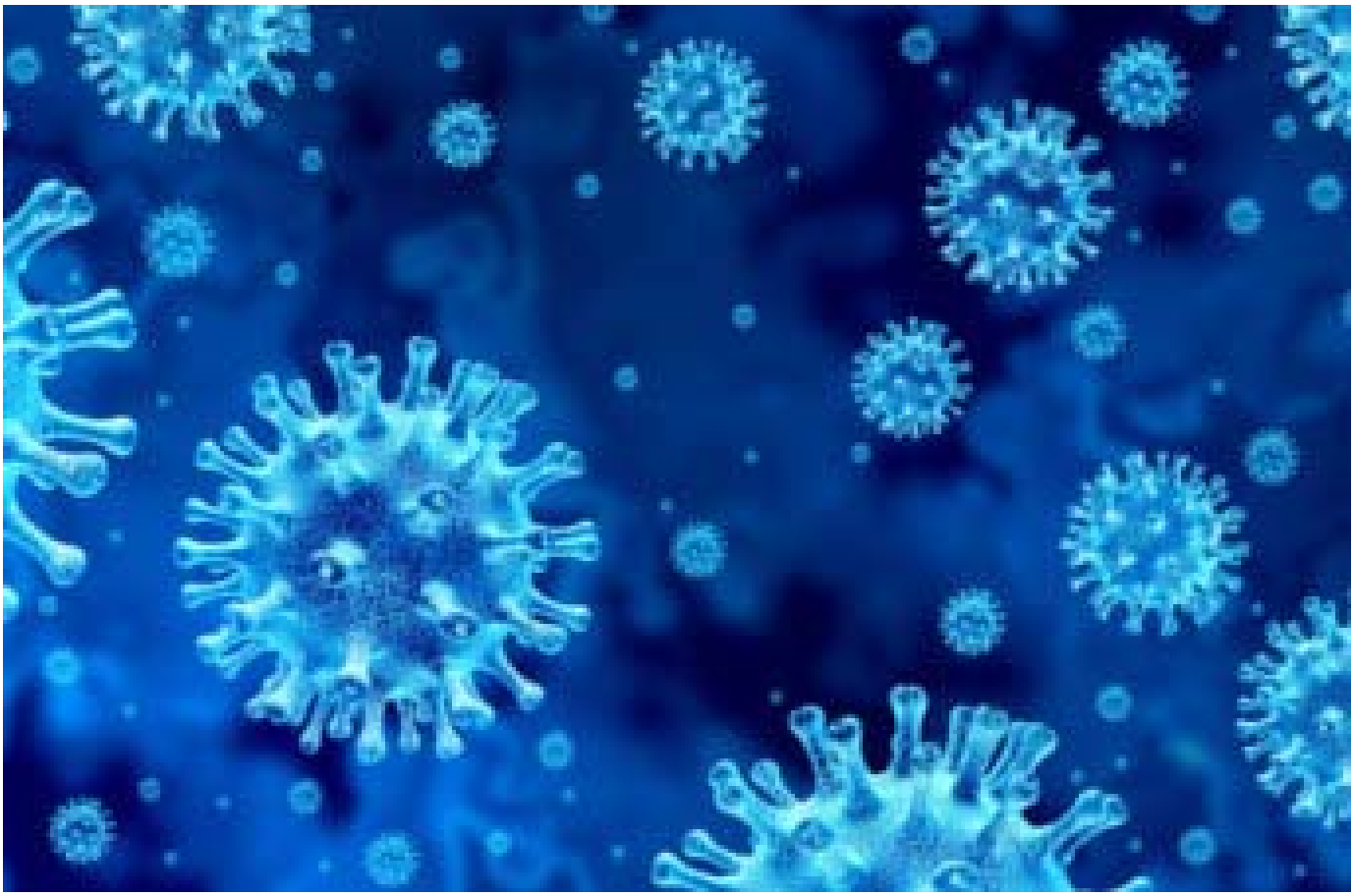
Further Reading



Merck Tests Molnupiravir, an Investigational Product, at the Lung Center of the Philippines While Large Ivermectin Trial Runs in Parallel


Mumbai Moves for
vermectin Prophylaxis
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