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Randomized Double-Blinded Clinical Trial at Sheba Medical Center: Ivermectin Materially Reduces COVID-19 Viral Shedding





By Francis February 13, 2021

eli schwartz ivermectin sheba medical center trialwatch leading



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A small but important randomized, double-blinded clinical trial sponsored by a top Israeli principal investigator and infectious disease physician embraced the use of ivermectin as a possible candidate to reduce viral shedding as well as lessen clinical deterioration for a targeted 100 early-onset, mild COVID-19 patients. The director of the Center for Geographic & Tropical Medicine at Sheba Medical Center, Sackler Faculty of Medicine, Tel Aviv, Professor Eli Schwartz, conducted this clinical trial starting in the summer. TrialSite spoke with Professor Schwartz in November, and he was still enrolling patients; however, he was recently able to conclude the study and report on the results on Vimeo. The study's takeaway: ivermectin significantly reduces the viral shedding overall in patients with COVID-19. Moreover, while the patient sample wasn't sufficiently sized, the data did reveal that the drug typically used to treat parasites can reduce infectivity duration. Professor Eli Schwartz concludes that more research is needed to capitalize on this promising drug's potential to significantly impact public health during the pandemic. For example, the drug shows potential to treat COVID-19 patients who, for whatever reasons, cannot get vaccinated; and of course, in the developing world where vaccination may be out into the future. Note that the study results have only been summarized by the Principal investigator and that they must be reviewed by the biomedical scientific community.

TrialSite introduced this important clinical trial originally back on June 15, introducing Dr. Eli Schwartz, the prominent researcher and physician who runs Israel's only tropical medicine institute. *TrialSite* notes that this study A) hasn't been peer-reviewed; B) nor has it been written up and uploaded to pre-print server and that C) it's currently only Professor Schwartz summarizing his findings for the world via *Vimeo* video presentation. *TrialSite* qualifies that this study information cannot be considered complete until the results are reviewed by the scientific community.

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The Study

Sponsored by Sheba Medical Center and led by Principal Investigator Professor Schwartz, this study investigated the FDA-approved broad-spectrum antiparasitic agent, which also has antiviral and anti-inflammatory activity. In this randomized controlled trial, the Sheba Medical Center team sought to evaluate the effect of ivermectin on the reduction of viral shedding among mild to











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patients ultimately, but the study was delayed due to recruitment challenges.

Initially targeting 100 participants, the study team was ultimately able to recruit 116 patients. However, due to dropouts and admission technicalities, the final study patient count was 49 patients diagnosed with COVID-19 in the ivermectin group of the study and 45 in the placebo group.

Dosages of ivermectin were based on body weight and administered for three days in oral tablet form. The placebo group received as many tablets for as many days. Dosages ranged from 150 to 300 ug/kg per day for three (3) days.

Targeted endpoints included 1) Viral Clearance at Day 6; 2) Viral shedding duration determined by 14 days post-intervention and C) Symptom clearance time (determined until 14 days post-intervention).

The Results

Overall, ivermectin shows promise, improving viral shedding as compared to the placebo group. Note that due to sampling sizes, assessing the key second measure, clinical deterioration, was challenging, but the data generated did point to the need for further study.

Negative Samples at (Ct>30) from initiation of treatment

	Ivermectin (n=49)	Placebo (n=40)	P value
Negative at day 4	15/26 (57%)	7/22 (31%)	0.08
Negative at day 6	33/49 (67%)	20/45 (44%)	0.03
Negative at day 8	39/49 (86%)	25/45 (53%)	0.03
Negative at day 10	40/49 (81%)	27/45 (60%)	0.02

As can be reviewed above, the difference between the ivermectin and placebo group is clearly significant. The P-value is a bit higher in the first data set as there are fewer samples. However, by day 6 of the study, there is a clear difference between the randomized, doubleblind ivermectin group and the placebo group. Ivermectin is accelerating the reduction of viral shedding.

Professor Schwartz and team ran a multivariable logistic regression feeding the model with a number of assumptions to conclude that with the adjusted odds ratio of Ct>30 at day 6 for the ivermectin group in the study was 3.37-fold higher than was for the placebo group. The study shows statistically the patient in the ivermectin group has odds more than three times greater than the patient in the placebo group to arrive at a negative reading (no viral shedding). According to Dr. Schwartz, this is highly significant.

Although no patient in the ivermectin group required hospitalization (while two in the placebo group in fact did require hospitalization), the sample size was too small and further research is required.

Conclusion

Dr. Schwartz concluded in his presentation that the data reveals that ivermectin in fact demonstrates anti-SARS-CoV-2 activity reducing the viral shedding period and evidences the reduction of infectivity time. There is an insufficient sample size for measuring disease progression but he concludes that ivermectin could have a significant impact on public health.

This well-known tropical disease research posits that in much of the developing world it will be a long time before mass vaccines occur. He suggests ivermectin could be a significant medicinal tool to help control the pandemic. Isolation periods hamper human productivity. If this period can be reduced, thus freeing up people to go back to work sooner has major implications.

Professor Schwartz reminds all that ivermectin is an incredibly safe drug at known dosages. Hundreds of millions have been treated and the dosages used in the COVID-19 studies chronicled by *TrialSite*, including this one, fall within the range used to target parasite indications. Note that the dosages may be higher but not substantially, according to Schwartz. No adverse events were observed in this study.

Sheba Medical Center

The largest hospital in Israel, Sheba Medical Center's hospital is ranked the 9th best hospital in the entire world. For more information follow the <u>link</u>.

Lead Research/Investigator











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review and ultimately perhaps submit the findings to a peer-review journal. These findings cannot be considered accepted by the world's medical community until they are peer-reviewed and ideally published in a reputable medical or scientific journal.



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