Unitaid, Part of the World Health Organization Funding Ivermectin Research Targeting COVID-19 led by British Expert

DEC 29, 2020 | BLOG, NEWS

Just recently ,Dr. Andrew Hill, Sr. Visiting Fellow, Department of

Pharmacology, University of Liverpool, shared on YouTube an interim, meta-analysis revealing the significant potential of Ivermectin as a treatment targeting SARS-CoV-2, the virus behind COVID-19. Dr. Hill's current meta-analysis study is funded ongoing by Unitaid, part of the World Health Organization's ACT Accelerator initiative to improve access to COVID-19 treatment and diagnostics. The researcher's meta-analysis, while still ongoing, points toward significant promise for Ivermectin, as a low cost, widely available therapy potentially useful targeting COVID-19. What are his findings thus far? Well, this meta-analysis involving 11 randomized controlled trials associated with 1,452 patients evidences A) Faster time to viral clearance; B) Shorter duration of hospitalization; C) 43% higher rates of clinical recovery; and D) 83% improvement in survival rates. What's next? A few big Ivermectin studies will produce results within weeks. Then, he'll approach the 3,000 patient number: that was the figure initially used as a basis for the Remdesivir authorization.

TrialSite offers a link to the *YouTube* page **Ivermectin meta-analysis by Dr. Andrew Hill – YouTube** showcasing Dr. Hill's findings. *TrialSite* also breaks down this situation, so more people can understand the growing momentum behind Ivermectin as a safe and effective treatment targeting COVID-19. Sort of a social movement at this point, the stakes are critically high that low cost, widely available options are introduced along with vaccines and of course sophisticated novel drug development. The global marketplace demands such options to combat the COVID-19 contagion. Life, liberty, and economy hangs in the balance.

Dr. Hill's Ivermectin research is funded by Unitaid—what is this organization?

A hosted partnership of the World Health Organization (WHO), **Unitaid** is an international organization that invests in innovations to prevent, diagnose, and treat HIV/AIDS, tuberculosis and malaria more quickly, affordably and effectively, The organization seeks to access diagnostics and treatment for HIV co-infections, such as hepatitis C and human papillomavirus.

Founded in 2006, the organization is known to fund the last steps of

research and development for new drugs, diagnostics and disease-preventing tools; they take on projects to help produce data supporting guidelines for the drug's use while championing more affordable generic medicines to enter the marketplace in low-and middle-income countries. The group was actually established by a handful of national governments, including Brazil, Chile, France, Norway, and the United Kingdom.

What is the Access to COVID-19 Tools (ACT) Accelerator?

The ACT Accelerator, launched by WHO and partners, supports the fastest, most coordinated, and successful global effort in history to develop tools to fight disease according to the organization's website. The ACT-Accelerator is on the cusp of securing a way to end the acute phase of the pandemic by deploying the tests, treatments and vaccines the world needs.

Recent contributions bring the total committed to over $5.6 billion US.

What does Dr. Hill Discuss in his presentation?

He recently conducted an extensive meta-analysis of Ivermectin as a targeted therapy against COVID-19. As a number of jurisdictions have already authorized the drug at least for early onset use in mild-to-moderate COVID-19 cases, a total of over 56 clinical trials are now ongoing.

What is his hypothesis?

Although Dr. Hill declared he doesn't have enough data for any declarative claims as of yet, he is getting closer. Perhaps the aggregate data made possible by the meta-analysis was sufficient? He notes via *YouTube* that the present clinical trials are in the size of between 100 and 500 participants. His key research question: "Is there enough clinical evidence to support the worldwide approval of Ivermectin to treat COVID-19?" As it turns out, he'll need another couple clinical trials to be in a position to make his recommendations. Those studies, conducted in Brazil, Argentina and Colombia, will be done within weeks.

How many randomized controlled studies has Dr. Hill analyzed?

11

Why didn't he include the many good observational studies such as the ICON study published in peer-review journal Chest?

Evidence from randomized controlled studies are the "Gold Standard" and thus carry the most evidentiary weight. Observational studies can be valuable to support a hypothesis but they are not sufficient by themselves.

What are his targeted endpoints?

In pursuing this question, Dr. Hill looked to the following endpoints: A) time to viral clearance as measured by PCR; B) time to clinical recovery; C) duration of hospitalization; and D) survival.

What databases did Dr. Hill review for the study?

The team used PUBMED, EMBASE, preprint databases, Coronavirus Antiviral Research Database (CoV-EDB), WHO clinical trials website, and country level clinical trials websites.

Has Dr. Hill found Ivermectin investigators helpful?

Yes. Absolutely. He pointed out that a good collaborative ecosystem has emerged.

In what nations are the 11 studies occurring?

Egypt, Iraq, Iran, Bangladesh, Argentina, Spain, and others.

What analysis did the researcher use?

For endpoint testing, the meta-analysis embraced by the British investigator included Cochran Mantel-Haenszel testing with inverse variance weighting and random effects modeling; this was subsequently used to compare outcomes between Ivermectin and the control treatment.

What are the high level summary of findings?

First, they found faster viral clearance across the largest studies in the

Ivermectin group versus the control group. For example, in three Egyptian studies, Ivermectin beat the control group each and every time. In the first study "*Egypt Elgazzar et al Moderate*," the control group's viral clearance was 10 days and the ivermectin group 5 days ($p<0.001$). While in the "*Egypt Elgazzar et al Severe*" the control group viral clearance averaged 12 days while the Ivermectin group was down to 6 days ($p<0.001$). In the "*Bangladesh Ahmed et al*" study, the control group time to clearance was 12.7 days with the Ivermectin group at 9.7 days ($p=0.02$).

Measuring hospital discharge or clinical recovery led to the observation that the largest studies with the highest doses of Ivermectin showed the most notable results.

For example, in the study "*Egypt Elgazzar et al moderate*," patients in the Ivermectin group scored significantly better than the control group (Ivermectin was 5 days and the control group 15 days, $p<0.001$). And in "*Egypt Elgazzar et al*," the patients on Ivermectin only experienced only 6 days for clinical recovery while the control group took only 18 days.

Put another way Dr. Hill's meta-analysis for clinical recovery reveals that those patients that were part of the Ivermectin were 43% more likely to have a faster clinical recovery than those on the control group (95% C.I. 21-67%) $p<0.0001$.

What about Survival Benefits? Well, according to Dr. Hill's meta-analysis, those in the Ivermectin group according to the data show greater survival (that is, staying alive). For example, out of 573 patients, only 8 died (5%) while in the control group of 510 44 died (17%). Hence the reduction in death rate equaled 83% (95% C.I. 65% to 92%), $p<0.0001$.

What are some limitations associated with the study?

Dr. Hill reminded the viewers that his meta-analysis includes a number of limitations, including the fact that they only had 11 randomized controlled studies for the analysis. He mentioned that there are another 45 clinical trials in process that are treating or planning on treating a total of 7.100 patients. He suggested the potential for "publication bias" and reports that several of the ivermectin trials were "open label" and exhibit potential

for investigator bias. Finally, he mentioned there was a range of doses and durations and the various endpoints differed by trial.

Has the interest in studying Ivermectin grown worldwide?

Absolutely. The meta-analysis completed was done on 11 trials totaling 1,452 patients. Now with at least 21 countries conducting Ivermectin studies targeting COVID-19, Dr. Hill and team will be analyzing randomized controlled studies in additional 45 trials across 21 countries and 7,100 patients. In the next 6 weeks, a 500 patient study in Brazil, a 450 patient study in Colombia and another large study in Argentina will be complete.

What is the evidence threshold?

It's not long until the meta-analysis reaches 3,000, which is the evidence base used for the original approval for remdesivir. It will be at that point that Dr. Hill can make formal recommendations for funding, etc.

Conclusion

The interim meta-analysis thus far involving 11 randomized controlled trials with 1,452 patients evidences A) Faster time to viral clearance; B) Shorter duration of hospitalization; C) 43% higher rates of clinical recovery; and D) 83% improvement in survival rates. Ivermectin shows considerable promise as a generic drug to be considered in a comprehensive approach to take on and overcome COVID-19. However, for any funded research, the researcher doesn't have enough data as of yet. But he is certainly closing in on the target.

Lead Research/Investigator

Andrew Hill, MD, Sr. Visiting Fellow, Department of Pharmacology, University of Liverpool

Call to Action: The World Health Organization's Unitaid invests in ongoing repurposing studies and could possibly include Ivermectin, a drug that by the month is studied by evem more clinical investigators across the world. The future looks bright for a potential economical treatment for COVID-19. Of course, Dr. Hill needs more data but he isn't far from that

moment. The *TrialSite* Network should monitor this one carefully.

Source: YouTube

10 COMMENTS

MATTHEW ELVEY ON DECEMBER 29, 2020 AT 8:49 PM

I appreciate that this criminal thinking is recounted:

"It's not long until the meta-analysis reaches 3,000, which is the evidence base used for the original approval for remdesivir. It will be at that point that Dr. Hill can make formal recommendations for funding, etc."

I, and surely every statistician or epidemiologist worth their salt knows p is far more important than n.

And that it's bullshit to argue otherwise. I've been on the receiving end of that bullshit argument a few times and every time, the bullshitter didn't get away with it. Even with a (so far) smaller n, the p for ivermectin is far far smaller (more impressive) than that for remdesivir.

When the FDA writes, as they do, that they'll work with researchers to figure out how large n has to be in their drug studies, what they're saying is, "buy us". The FDA has no objective way for determining n; it's apparently all about how crooked and rich the research backer is (how deep the pockets are), how big a bribe is paid, how greedy the regulators are. (If there were an algorithm, it would be a product of the federal gov't and both likely subject to disclosure under FOIA and derivable from already-public data.)