THE WAR ON GENERIC, REPURPOSED MEDICINES IN COVID-19: THE TOGETHER TRIAL

Pierre Kory, MPA, MD

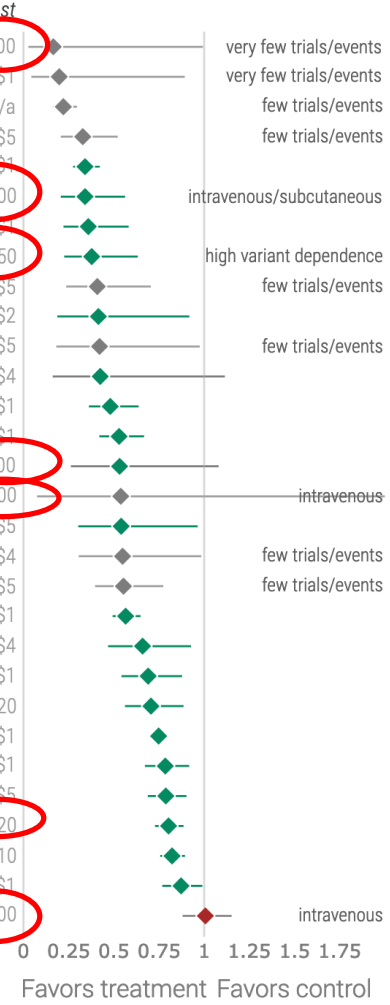
President, Chief Medical Officer

Front Line COVID-19 Critical Care Alliance

DESPITE OVER TWO DOZEN REPURPOSED MEDICATIONS WITH CLINICAL TRIALS SHOWING EFFICACY IN COVID, NONE ARE RECOMMENDED IN THE U.S.

All studies combined (pooled effects, all stages) c19early.com Jan 6, 2022

	Improvement, RR [CI]	Studies	Patients	Cost	
Paxlovid	**83%** 0.17 [0.03-0.99]	2	2,939	$700	very few trials/events
Iota-carragee..	**80%** 0.20 [0.04-0.89]	1	394	$1	very few trials/events
Proxalutamide	**78%** 0.22 [0.16-0.30]	3	1,223	n/a	few trials/events
Nigella Sativa	**67%** 0.33 [0.21-0.52]	4	1,291	$5	few trials/events
Ivermectin	**66%** 0.34 [0.27-0.42]	73	56,804	$1	
Casirivimab/i..	**66%** 0.34 [0.21-0.56]	14	39,07	$2,100	intravenous/subcutaneous
Melatonin	**64%** 0.36 [0.22-0.58]	11	13,517	$1	
Bamlanivimab	**62%** 0.38 [0.23-0.63]	11	23,33	$1,250	high variant dependence
Curcumin	**59%** 0.41 [0.24-0.70]	9	867	$5	few trials/events
Vitamin A	**59%** 0.41 [0.19-0.92]	6	15,923	$2	
Quercetin	**58%** 0.42 [0.18-0.98]	6	996	$5	few trials/events
Nitazoxanide	**58%** 0.42 [0.16-1.11]	7	1,508	$4	
Povidone-Iod..	**52%** 0.48 [0.36-0.64]	12	2,549	$1	
Zinc	**47%** 0.53 [0.42-0.67]	22	50,909	$1	
Molnupiravir	**47%** 0.53 [0.26-1.08]	6	3,015	$700	
Sotrovimab	**46%** 0.54 [0.08-3.85]	2	1,417	$2,100	intravenous
Antiandrogens	**46%** 0.54 [0.30-0.96]	8	5,900	$5	
Budesonide	**45%** 0.55 [0.31-0.98]	3	8,751	$4	few trials/events
Bromhexine	**45%** 0.55 [0.40-0.77]	5	291	$5	few trials/events
Vitamin D	**43%** 0.57 [0.49-0.65]	58	122,873	$1	
Fluvoxamine	**34%** 0.66 [0.47-0.93]	6	2,599	$4	
Colchicine	**31%** 0.69 [0.54-0.88]	12	17,762	$1	
Favipiravir	**29%** 0.71 [0.56-0.89]	23	5,866	$20	
Hydroxychlor..	**25%** 0.75 [0.71-0.79]	303	415,829	$1	
Aspirin	**21%** 0.79 [0.67-0.92]	23	66,304	$1	
Probiotics	**21%** 0.79 [0.69-0.90]	14	17,130	$5	
Remdesivir	**20%** 0.80 [0.73-0.89]	27	98,777	$3,120	
Metformin	**18%** 0.82 [0.76-0.89]	21	67,681	$10	
Vitamin C	**13%** 0.87 [0.77-0.99]	27	31,062	$1	
Conv. Plasma	**-1%** 1.01 [0.88-1.15]	14	15,607	$5,000	intravenous



CORPORATE TACTICS TO COUNTER "SCIENCE INCONVENIENT TO THEIR INTERESTS"

Union of Concerned Scientists

TAKE ACTION DONATE MENU

REPORTS & MULTIMEDIA / FEATURE

The Disinformation Playbook

A "Disinformation Playbook" has been used for decades by corporations to delay government action on matters that would adversely affect their income and profit.

- 1**. The Fake** - Conduct counterfeit science and try to pass it off as legitimate research
- 2. **The Blitz** - Harass scientists who speak out with results or views inconvenient for industry.
- 3**. The Diversion** - **Manufacture uncertainty about science where little or none exists.**
- 4**. The Screen** - Buy credibility through alliances with academia or professional societies.
- 5. **The Fix** - Manipulate government officials or processes to influence policy inappropriately.

PHARMACEUTICAL COMPANY "DISINFORMATION" TACTICS

- **"The Diversion" - Manufacture counterfeit science**
  - selectively publishing negative results while underreporting positive results
  - commission scientific studies with flawed methodologies biased toward predetermined results
  - planting ghostwritten articles in legitimate scientific journals

  These methods undermine the scientific process and can have serious public health and safety consequences

The AMERICAN SCHOLAR
PUBLISHED BY PHI BETA KAPPA

ARTICLE - SUMMER 2011

Flacking for Big Pharma

Drugmakers don't just compromise doctors; they also undermine top medical journals and skew medical r

By Harriet A. Washington | June 3, 2011

THE TOGETHER TRIAL – MARCH 30, 2022

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Effect of Early Treatment with Ivermectin among Patients with Covid-19

Gilmar Reis, M.D., Ph.D., Eduardo A.S.M. Silva, M.D., Ph.D., Daniela C.M. Silva, M.D., Ph.D., Lehana Thabane, Ph.D., Aline C. Milagres, R.N., Thiago S. Ferreira, M.D., Castilho V.Q. dos Santos, Vitoria H.S. Campos, Ana M.R. Nogueira, M.D., Ana P.F.G. de Almeida, M.D., Eduardo D. Callegari, M.D., Adhemar D.F. Neto, M.D., Ph.D., Leonardo C.M. Savassi, M.D., Ph.D., Maria I.C. Simplicio, B.Sc.Pharm., Luciene B. Ribeiro, R.N., Rosemary Oliveira, Ofir Harari, Ph.D., Jamie I. Forrest, Ph.D., M.P.H., Hinda Ruton, M.Sc., Sheila Sprague, Ph.D., Paula McKay, M.Sc., Christina M. Guo, B.Com., Karen Rowland-Yeo, Ph.D., Gordon H. Guyatt, M.D., David R. Boulware, M.D., M.P.H., Craig R. Rayner, Pharm.D., F.R.C.P.Edin., and Edward J. Mills, Ph.D., F.R.C.P. for the TOGETHER Investigators*

The New York Times

Ivermectin Does Not Reduce Risk of Covid Hospitalization, Large Study Finds

"At some point it will become a waste of resources to continue studying an unpromising approach," one expert said.

Los Angeles Times

SUBSCRIBE LOG IN

Latest: COVID-19 | Virus tracker | Hospitalizations | Vaccines | Newsletter

Column: Major study of ivermectin, the anti-vaccine crowd's latest COVID drug, finds 'no effect whatsoever'

CONFLICTS OF INTEREST UP THE WAZOO (that the FLCCC doesn't have)

- ***Possibly the largest financial conflict of interest of any trial to date.*** Disclosed conflicts of interest include: Pfizer, Merck, Bill & Melinda Gates Foundation, Australian Government, Rainwater Charitable Foundation, Fast Grants, Medicines Development for Global Health, Novaquest, Regeneron, Astrazeneca, Daichi Sankyo, Commonwealth Science and Research Organization, and Card Research. Many conflicts of interest appear unreported. For example, Unitaid is a sponsor *[Harper, togethertrial.com]*.
- ***Analysis done by a company that receives payment from and works closely with Pfizer.*** All analyses were done by Cytel. Cytel is a statistical modelling company that helps pharmaceutical companies get approval — they work very closely with Pfizer Cytel's software and services are used by the top 30 pharmaceutical companies
- A co-principal investigator works for Cytel and the Gates Foundation: *"The majority of the time I work for a company called Cytel, where I design clinical trials, predominantly for the Bill & Melinda Gates Foundation."*
- The Gates Foundation is a founding partner of GAVI, which took out Google ads telling people not to use ivermectin and a major funder of Unitaid, which may have modified the results of the Hill meta analysis in a way that prevented adoption
- ***Associated with MMS Holdings.*** The trial is associated with MMS Holdings whose mission includes helping pharmaceutical companies get approval and designing scientific studies that help them get approval. One of their clients is Pfizer
- ***Certara.*** One of the senior investigators was Dr. Craig Rayner, President of Integrated Drug Development at Certara - another company with a similar mission to MMS Holdings. They state on their website that: "Since 2014, our customers have received over 90% of new drug and biologic approvals by the FDA." One of their clients is Pfizer

Ivermectin Prophylaxis Used for COVID-19: A Citywide, Prospective, Observational Study of 223,128 Subjects Using Propensity Score Matching

Correction

It has come to the attention of the journal that several authors failed to disclose all relevant conflicts of interest when submitting this article. As a result, Cureus is issuing the following erratum and updating the relevant conflict of interest disclosures to ensure these conflicts of interest are properly described as recommended by the ICMJ:

- **Lucy Kerr:** Paid consultant for both Vitamedic, an ivermectin manufacturer, and Médicos Pela Vida (MPV), an organization that promotes ivermectin as a treatment for COVID-19.
- **Flavio A. Cadegiani:** Paid consultant ($1,600.00 USD) for Vitamedic, an ivermectin manufacturer. Dr. Cadegiani is a founding member of the Front Line COVID-19 Critical Care Alliance (FLCCC), an organization that promotes ivermectin as a treatment for COVID-19.
- **Pierre Kory:** President and Chief Medical Officer of the Front Line COVID-19 Critical Care Alliance (FLCCC), an organization that promotes ivermectin as a treatment for COVID-19. Dr. Kory reports receiving payments from FLCCC. In February of 2022, Dr. Kory opened a private telehealth fee-based service to evaluate and treat patients with acute COVID, long haul COVID, and post-vaccination syndromes.
- **Jennifer A. Hibberd:** Co-founder of the Canadian Covid Care Alliance and World Council for Health, both of which discourage vaccination and encourage ivermectin as a treatment for COVID-19.
- **Juan J. Chamie-Quintero:** Contributor to the Front Line COVID-19 Critical Care Alliance (FLCCC) and lists the FLCCC as his employer on his LinkedIn page.

THE CAMPAIGN AGAINST GENERIC MEDICINES IS A WAR OF INFORMATION

- **Media attacks** on researchers… like me ☺
- Health agencies **sending bulletins** recommending against use to all U.S. doctors
- Media **censorship** of any mentions of efficacy (YouTube, Twitter, LinkedIn, FB, etc.
- Positive **studies of ivermectin and hydroxychloroquine retracted**
- Financial influence "**capture" of high-level researchers** (Dr. Andrew Hill)
- **Only "negative studies" are published** in high impact journals
  - WHO meta-analysis **dismisses the majority of the evidence base** – **FRAUDULENT**
  - 2 meta-analyses later published in "high-impact" medical journals – **ALSO FRAUDULENT**
  - All major meta-analyses conclude there is "**insufficient evidence**" to recommend
- Prolonged avoidance of funding of research into ivermectin – ACTIV 6??
  - Then agencies fund **clinical trials "designed to fail" (almost all investigators tied to Pharma)**

"THE DIVERSION" IS THE MOST IMPACTFUL TACTIC OF THE DISINFROMATION PLAYBOOK

- Definition: "manufacturing uncertainty where little or none exists"
- Pharma/BMGF fund LARGE randomized studies of generic medicines "designed to fail" (studies with flawed methodologies) is guaranteed publication in a "high impact medical journal"
  - Only "high impact medical journal" studies are publicized by "major media," articles of which echo across the world
  - These articles influence doctors, scientists, journalists, and laypeople across the world
  - The diversion is the single most powerful tactic to influence policy

The Four "High Impact" RCTs of Ivermectin

- March 2021. Lopez-Medina, ***JAMA***: ivermectin treated patients recovered in 10 days vs. 12 days in controls (not statistically significant)
- July 2021. Vallejos et al. ***BMC Infectious Disease***: 5.6% of ivm treated patients went to hospital vs. 8.4% of controls (not statistically significant)
- February 2022. Loon Lim et al. ***JAMA.*** Although ivermectin treated patients ended up needing "oxygen supplementation?" more often (21.6% vs. 17.3%, they needed less mechanical ventilation (1.7% vs. 4.0%, p=.17), icu admission (2.4% vs. 3.2%) and death (1.2% vs. 4.0%, **p=.09 - this latter difference is striking).**
- March 2022. Ries et al. ***NEJM.*** Found that ivermectin treated patients went to the ER for > 6 hours or were hospitalized less than controls (14.7% vs. 16.3%) and died less than controls (18% reduction).

FATAL FLAW #1 – conducting the trial in an area where ivermectin use was rampant.. And not having use as an exclusion criteria???

Alexandros Marinos @alexandrosM · Mar 31

Perhaps ivermectin was not something used commonly in that area at the time? Sounds like a reasonable explanation. Except for 3 facts:

1. Ivermectin is available over the counter in Brazil.

Mauricio Rodriguez @ColombianRoast · Aug 22, 2021

Replying to @alexandrosM and @mrich0312

Bought it OTC here in São Paulo, Brazil. Around US$5 if I remember correctly.

Brazil was promoting early treatment

Alexandros Marinos @alexandrosM · Mar 31

2. The Brazilian government was recommending it as a COVID treatment, as part of its early treatment kit:

> **AssocAmerPhys&Surg** @AAPSonline · Sep 26, 2020
>
> Brazil "plans 'D-Day' against Covid-19. The campaign will ask that, in the first symptoms, people seek a doctor and request early treatment with COVID-Kit which includes hydroxychloroquine, chloroquine, azithromycin, ivermectin and zinc." falape.com/governo-planej...

Sales of IVM were skyrocketing in the region

Alexandros Marinos @alexandrosM · Mar 31

3. As a result, sales of ivermectin in the area where the trial was taking place were NINE TIMES higher than normal. (screenshot via Google translate)

otempo.com.br/interessa/vend...

Portal The Time It > Interests > Article

'KIT COVID'

Sales of ivermectin increases ninefold in Minas and concerns about health risk

WhatsApp groups encourage the use of the drug in "early treatment" against Covid-19, which has no scientific evidence and can cause harm

By GABRIEL RODRIGUES
05/04/21 - 03h00

Google News

Principal Investigator:

At the time we did our study, IVM was not particularly popular for use in Minais Gerais. Even if some patients did access IVM, the fact that it is blinded should still maintain balance.

The AMERICAN SCHOLAR
PUBLISHED BY PHI BETA KAPPA

ARTICLE - SUMMER 2011

Flacking for Big Pharma

Drugmakers don't just compromise doctors; they also undermine top medical journals and skew medical r

By Harriet A. Washington | June 3, 2011

UNDERDOSING CONTROLS IN PHARMA TRIALS IS A KEY TACTIC IN HEAD TO HEAD TRIALS

FATAL FLAW #2 and #3.. DOSING And Duration

- **The started the trial with a single dose to be given at 0.2mg/kg.** For, you know.. Parasites! They "used dosing similar to parasite dosing." This is another tell – they know it is an anti-viral
- Then they **changed it to 0.4mg/kg** for three days **"after feedback from advocacy groups"** – late night email to me, no context given, no knowledge of gamma. At the time of the trial, Brazil MD's – way higher doses used (we soon changed to 0.4-0.6 for 5 days or until recovered)
- But why only 3 days?
  - Molnupiravir – an anti viral – 5 day dosing
  - Paxlovid – an anti-viral – 5 day dosing
  - Oseltemavir – 7 day dosing
  - Lopinavir/ritonavir – 14 day dosing

More "Funny Business" with Dosing

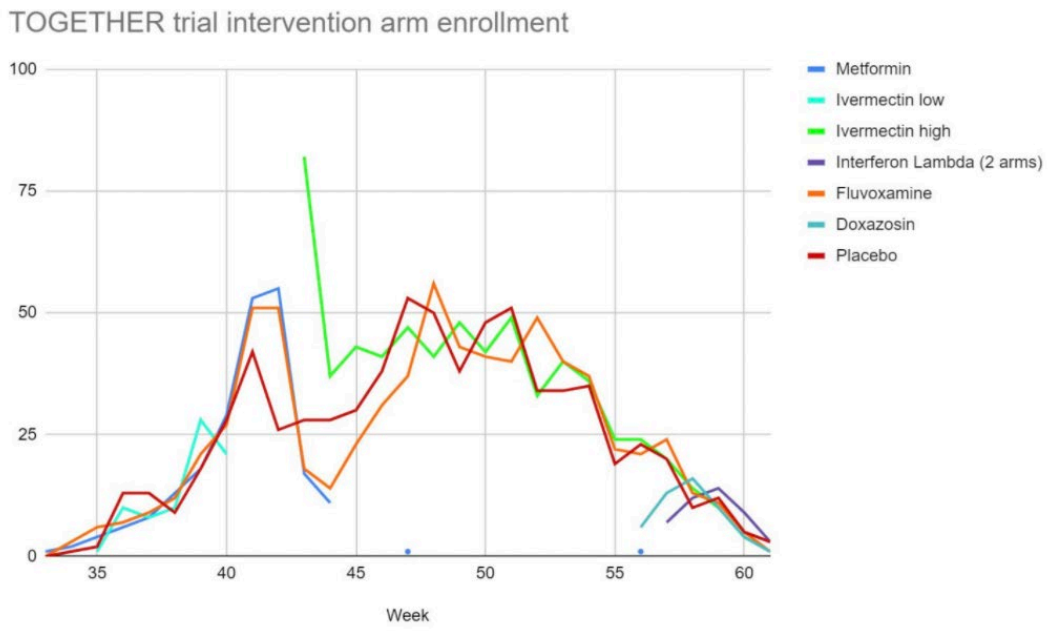
- Our "advocacy group" has recommended IVM to be taken on a full stomach
  - In the TOGETHER trial.. they specified on an empty stomach

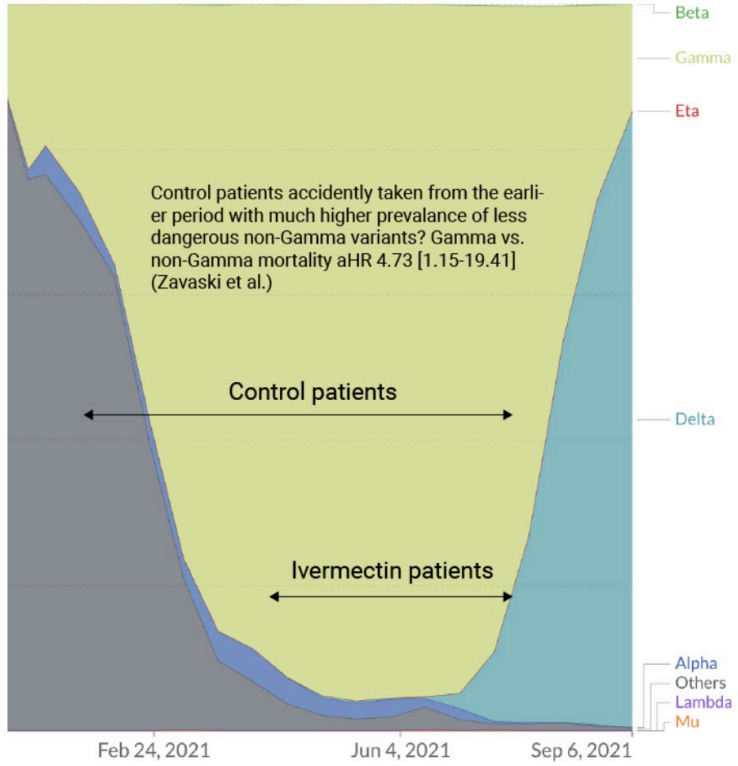
- Further, they had a weight limit of 90kg at 0.4mg/kg =198 pounds
  - Every patient over 198 pounds… thus got less than 0.4 KG
  - 50% of patients had BMI ≥30. Much greater efficacy was seen in the low BMI subgroup (RR 0.77 vs 0.98).

- These 4 issues are CLEARLY an attempt for this trial to use the lowest dose possible that they could get away with to achieve a non-successful result
  - attempting a one-day trial
  - converting to 3 days only
  - specifying an empty stomach,
  - limiting 0.4mg/kg dose to 198 pound limit

PLACEBO PATIENTS AND IVM PATIENTS WERE NOT ENROLLED AT THE SAME TIME - BUMMER

- Control group patients were enrolled at earlier time points than the ivermectin patients, when far less deadly variants predominated





THE OVERPERFORMING MISSING DAY-OF-ONSET PATIENTS

- Note that the total patients in the IVM and Placebo column should be 679

Subgroup	Ivermectin	Placebo	Relative Risk (95% Bayesian Credible Interval)
	no. of patients with event/total no.		
Age			
≤50 yr	38/335	39/347	1.01 (0.66–1.53)
>50 yr	53/295	66/283	0.77 (0.56–1.06)
Body-mass index			
<30	38/345	48/333	0.77 (0.51–1.14)
≥30	60/330	63/339	0.98 (0.71–1.34)
Cardiovascular disease			
No	53/397	58/407	0.94 (0.66–1.32)
Yes	47/282	53/272	0.86 (0.60–1.22)
Lung disease			
No	96/665	106/664	0.90 (0.70–1.17)
Yes	4/14	5/14	0.83 (0.28–2.26)
Sex			
Female	47/383	59/408	0.85 (0.59–1.21)
Male	53/296	52/271	0.93 (0.66–1.32)
Smoking status			
Current	5/50	5/59	1.18 (0.38–3.63)
Former	15/94	13/73	0.89 (0.46–1.75)
Never	80/535	93/545	0.88 (0.67–1.15)
Time since onset of symptoms			
0–3 days	41/282	35/276	1.14 (0.76–1.74)
4–7 days	43/242	43/241	1.00 (0.68–1.46)
	542?	571?	

When you "reverse calculate" the outcomes for patients with "unknown days since onset," you find they had a 50% reduction in the primary outcome if treated with ivermectin

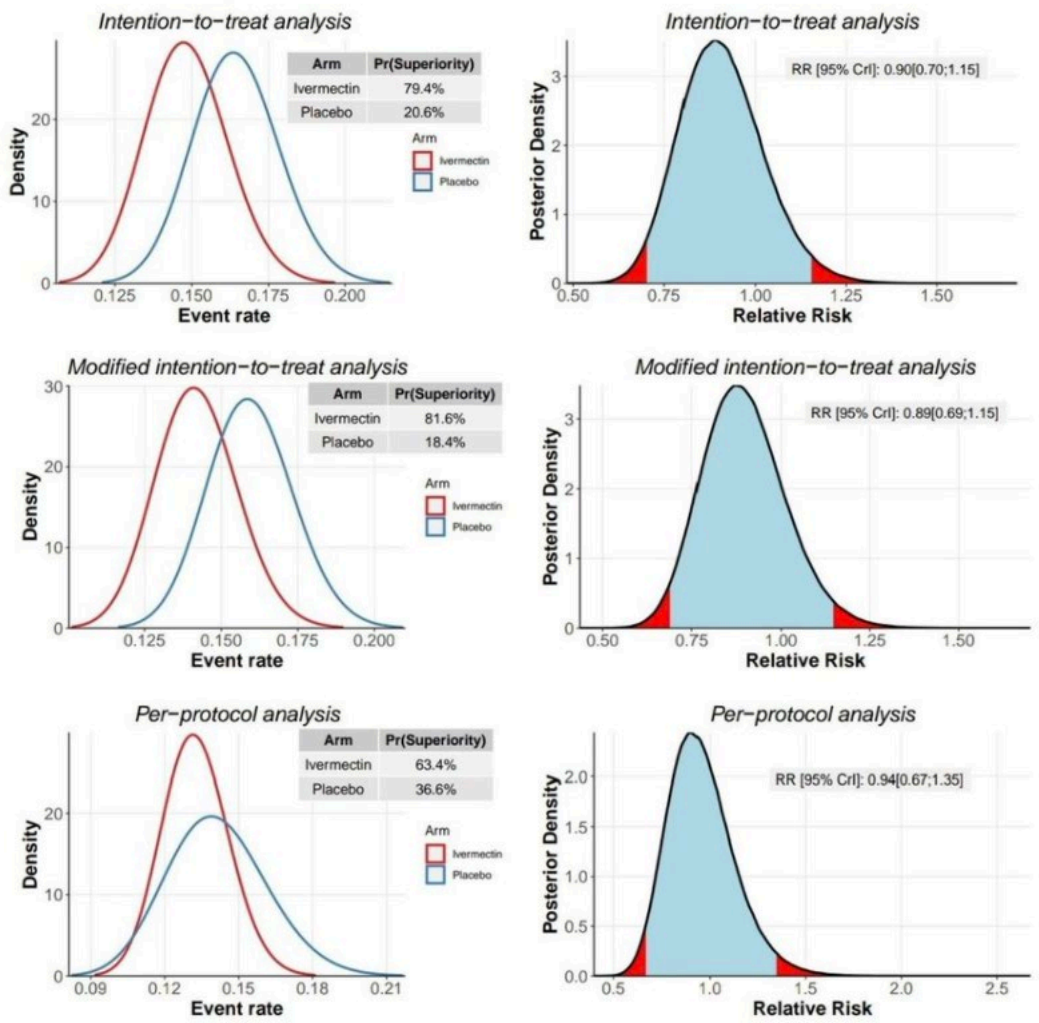
THE OVER PERFORMING 3-DAY PLACEBO GROUP?

Alexandros Marinos
@alexandrosM

TOGETHER trial: The Magical 3-day Placebo Group 🧵

Why is the per-protocol placebo (blue) curve shifted left compared to ITT/mITT placebo groups? It appears the per-protocol analysis gives lower superiority probability not because ivm did worse, but because placebo did better.

Figure S6: Probability of efficacy and Bayesian relative risk of Covid-19 hospitalization or extended emergency room observation for ivermectin vs. placebo



LEGEND: In the ivermectin group, 14.7% (100 of 679) of participants experienced a primary outcome event compared with 16.3% (111 of 679) in the placebo group. By intention-to-treat analysis, the Relative Risk was 0.90; 95% Bayesian Credible Interval [BCI]: 0.70 – 1.16) for ivermectin reducing the primary outcome of hospitalizations or prolonged emergency setting observations of >6 hours. The probability that the event rate was lower in the ivermectin group compared to placebo was 79.4% for the intention-to-treat population, 81.7% for the modified intention-to-treat population, and 63.4% in the per-protocol analysis.

FLCCC ALLIANCE

Trial Completed 7 Months Ago.. Why did it take 7 months to publish with the entire world waiting?

- An incredible delay given the importance of the result in guiding treatment

- ***Large change in results from previously released data.*** The published results are very different from the previously released results, for example 100/679 vs. 86/677 for the primary outcome ivermectin events. The mortality RR changed from 0.82 to [0.88/0.81/0.80] for [Table 2/Table 2 AE/Table S6].

7 MONTHS LATER, "VERE IS ZE DATA"?

- The trialists always stipulated they would make the dataset publicly available on request
  - This is a MAJOR, KEY ISSUE with RCTs and Big Pharma – the lack of transparency has led to major shenanigans over decades (Pfizer vaccine trial anyone?)

- Yet – they have not released the data to anyone, even their funders, since completion, despite repeated requests from many groups
- Now they have changed how that data can be accessed – they are releasing it to a 3rd party and then researchers have to apply to that 3rd party

TOO MANY ISSUES REMAIN TO TALK ABOUT… HOW ABOUT JUST 3 MORE

- Dr. Cadegiani:
  - **Brazil is the LARGEST SINGLE BUYER of drugs** and vaccines in the world. The national health system has the ability to buy almost half trillion dollars per year. Contracts of dozens of billions of dollars are common. Many of them with Pfizer.
  - Easy to **conduct a trial in Brazil with corrupted CROs** (I have proof of that) to allow these conclusions.

- ***Anomalous results from the same region.*** A local Brazilian investigator reports that the study was conducted in almost the same time and location as the Brazilian component of the molnupiravir trial. Notably, **molnupiravir's EUA relied on the unusually higher efficacy observed in Brazil.**

THIS JUST IN.. THEY CHANGED THE DATA YESTERDAY.. AFTER PUBLICATION??

Table S6: Adverse Events by Grade, MedDRA Type and Treatment Group

Characteristic	Ivermectin			Placebo		
	Grade 1 or 2, N = 82[1]	Grade 3 or 4, N = 61[1]	Grade 5, N = 20[1]	Grade 1 or 2, N = 105[1]	Grade 3 or 4, N = 71[1]	Grade 5, N = 25[1]
Standard of care term (MedDRA)						
Gastrointestinal disorders	3 (3.7%)	0 (0%)	0 (0%)	6 (5.7%)	1 (1.4%)	0 (0%)
General disorders and administration site conditions	31 (38%)	4 (6.6%)	1 (5.0%)	39 (37%)	1 (1.4%)	1 (4.0%)
Immune system disorders	1 (1.2%)	0 (0%)	0 (0%)	0	0	0
Infections and infestations	15 (18%)	55 (90%)	19 (95%)	28 (27%)	64 (90%)	21 (84%)
Injury, poisoning and procedural complications	1 (1.2%)	0 (0%)	0 (0%)	0	0	0
Metabolism and nutrition disorders	2 (2.4%)	1 (1.6%)	0 (0%)	2 (1.9%)	0 (0%)	0 (0%)
Musculoskeletal and connective tissue disorders	7 (8.5%)	1 (1.6%)	0 (0%)	5 (4.%)	1 (1.4%)	0 (0%)
Nervous system disorders	3 (3.7%)	0 (0%)	0 (0%)	5 (4.8%)	0 (0%)	0 (0%)
Psychiatric disorders	2 (2.4%)	0 (0%)	0 (0%)	0	0	0
Reproductive system and breast disorders	1 (1.2%)	0 (0%)	0 (0%)	0	0	0
Respiratory, thoracic and mediastinal disorders	11 (13%)	0 (0%)	0 (0%)	16 (15%)	1 (1.4%)	1 (4.0%)
Skin and subcutaneous tissue disorders	1 (1.2%)	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	0 (0%)
Vascular disorders	4 (4.9%)	0 (0%)	0 (0%)	1 (1.0%)	1 (1.4%)	0 (0%)
Cardiac disorders	0	0	0	0 (0%)	1 (1.4%)	2 (8.0%)
Ear and labyrinth disorders	0	0	0	1 (1.0%)	0 (0%)	0 (0%)
Hepatobiliary disorders	0	0	0	0 (0%)	1 (1.4%)	0 (0%)
Renal and urinary disorders	0	0	0	1 (1.0%)	0 (0%)	0 (0%)

[1]n (%)

Table S6: Adverse Events by Grade, MedDRA Type and Treatment Group

Characteristic	Ivermectin			Placebo		
	Grade 1 or 2, N = 82[1]	Grade 3 or 4, N = 60[1]	Grade 5, N = 21[1]	Grade 1 or 2, N = 105[1]	Grade 3 or 4, N = 71[1]	Grade 5, N = 24[1]
Standard of care term (MedDRA)						
Gastrointestinal disorders	3 (3.7%)	0 (0%)	0 (0%)	6 (5.7%)	1 (1.4%)	0 (0%)
General disorders and administration site conditions	31 (38%)	4 (6.7%)	1 (4.8%)	39 (37%)	1 (1.4%)	1 (4.2%)
Immune system disorders	1 (1.2%)	0 (0%)	0 (0%)	0	0	0
Infections and infestations	15 (18%)	54 (90%)	20 (95%)	28 (27%)	64 (90%)	21 (88%)
Injury, poisoning and procedural complications	1 (1.2%)	0 (0%)	0 (0%)	0	0	0
Metabolism and nutrition disorders	2 (2.4%)	1 (1.7%)	0 (0%)	2 (1.9%)	0 (0%)	0 (0%)
Musculoskeletal and connective tissue disorders	7 (8.5%)	1 (1.7%)	0 (0%)	5 (4.8%)	1 (1.4%)	0 (0%)
Nervous system disorders	3 (3.7%)	0 (0%)	0 (0%)	5 (4.8%)	0 (0%)	0 (0%)
Psychiatric disorders	2 (2.4%)	0 (0%)	0 (0%)	0	0	0
Reproductive system and breast disorders	1 (1.2%)	0 (0%)	0 (0%)	0	0	0
Respiratory, thoracic and mediastinal disorders	11 (13%)	0 (0%)	0 (0%)	16 (15%)	1 (1.4%)	0 (0%)
Skin and subcutaneous tissue disorders	1 (1.2%)	0 (0%)	0 (0%)	1 (1.0%)	0 (0%)	0 (0%)
Vascular disorders	4 (4.9%)	0 (0%)	0 (0%)	1 (1.0%)	1 (1.4%)	0 (0%)
Cardiac disorders	0	0	0	0 (0%)	1 (1.4%)	2 (8.3%)
Ear and labyrinth disorders	0	0	0	1 (1.0%)	0 (0%)	0 (0%)
Hepatobiliary disorders	0	0	0	0 (0%)	1 (1.4%)	0 (0%)
Renal and urinary disorders	0	0	0	1 (1.0%)	0 (0%)	0 (0%)

[1]n (%)

CONFLICTED RESEARCHERS WITH "NOTHING TO HIDE" START TALKING FROM BOTH SIDES OF THEIR MOUTH

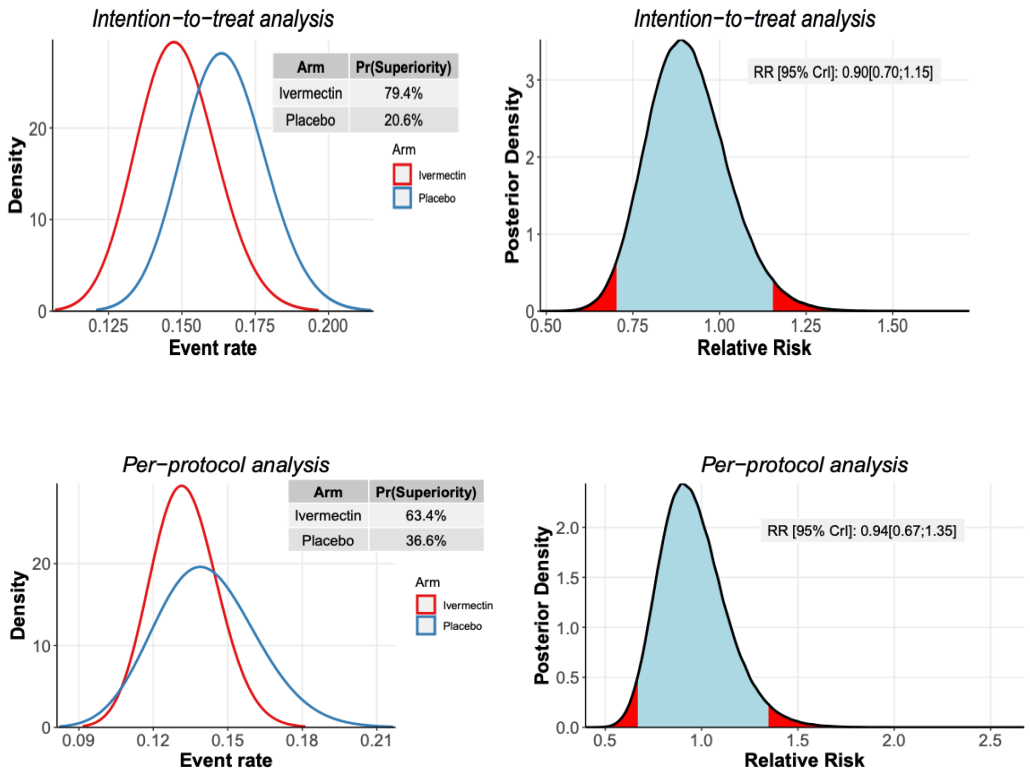
- Ed Mills, Principal Investigator: Prior to trial, he has made multiple public and private (email) statements that those who recommend ivermectin are "advocates" and "he does not believe it works" (does not call us clinicians or researchers or... COVID experts)

- IN HIS TOGETHER TRIAL PRESENTATION FROM 7 MONTHS AGO, MADE THESE COMMENTS:
- "we got a lot of criticism for single day dosing" (Criticism? How about helpful guidance?)

- "we found that it had no effect, WHATSOEVER, on our primary outcome" 86/677 (12.7%) vs 95/678 (14.0%) (No benefit? Oh, you mean "statistically significant?"

- "we do not see the treatment benefit that a lot of advocates believe should have been seen"

7 MONTHS LATER, DESPITE SHENANIGANS…BAYESIAN STATISTICS FINDS HIGH LIKELIHOOD OF SUPERIORITY



LEGEND: In the ivermectin group, 14.7% (100 of 679) of participants experienced a primary outcome event compared with 16.3% (111 of 679) in the placebo group. By intention-to-treat analysis, the Relative Risk was 0.90; 95% Bayesian Credible Interval [BCI]: 0.70 – 1.16) for ivermectin reducing the primary outcome of hospitalizations or prolonged emergency setting observations of >6 hours. The probability that the event rate was lower in the ivermectin group compared to placebo was 79.4% for the intention-to-treat population, 81.7% for the modified intention-to-treat population, and 63.4% in the per-protocol analysis.

THE WALL STREET JOURNAL.

English Edition ▾ | Print Edition | Video | Podcasts | Latest Headlines

cs Economy Business Tech Markets Opinion Books & Arts Real Estate Life & Work

Words of the Principal Investigator when asked about this issue for the Wall Street Journal 10 days ago:

"There was no indication that ivermectin is clinically useful"

What he says in his NIH presentation and now privately (and what the data shows in the paper)

"I presented this a couple weeks ago at the NIH Collaboratory Rounds and, if they listened, I advocate that actually, there is a clear signal that IVM works in COVID patients, just that our study didn't achieve significance. In particular, there was a 17% reduction in hospitalizations that would be significant if more patients were added. I really don't view our study as negative and, also in that talk, you will hear me retract previous statements where I had been previously negative. I think if we had continued randomizing a few hundred more patients, it would have likely been significant."

U.S. INTERNATIONAL CANADA ESPAÑOL 中文

The New York Times

Ivermectin Does Not Reduce Risk of Covid Hospitalization, Large Study Finds

"At some point it will become a waste of resources to continue studying an unpromising approach," one expert said.

- This week: "**There's really no sign of any benefit,"** said Dr. David Boulware, an infectious-disease expert at the University of Minnesota
- "**Now that people can dive into the details and the data, hopefully that will steer the majority of doctors away from ivermectin towards other therapies,"** Dr. Boulware said.

The New York Times

Ivermectin Does Not Reduce Risk of Covid Hospitalization, Large Study Finds

- "On their second review, Dr. Hill and his colleagues focused on the studies least likely to be biased. In that stricter survey, ivermectin's benefit vanished.
- "Still, even the best studies on ivermectin and Covid were small, with a few hundred volunteers at most. Small studies can be vulnerable to statistical flukes that suggest positive effects where none actually exist. But larger studies on ivermectin were underway at the time, and those promised to be more rigorous."

JAMA® Search All Enter Search Term

This Issue | Views 991,455 | Citations 28 | Altmetric 10045 | Comments 15

Download PDF | More | CME & MOC | Cite This | Permissions

Original Investigation FREE

March 4, 2021

Effect of Ivermectin on Time to Resolution of Symptoms Among Adults With Mild COVID-19

A Randomized Clinical Trial

Eduardo López-Medina, MD, MSc[1,2,3]; Pío López, MD[1,2]; Isabel C. Hurtado, MD[2,4]; et al

» Author Affiliations

JAMA. 2021;325(14):1426-1435. doi:10.1001/jama.2021.3071

Results Among 400 patients who were randomized in the primary analysis population (median age, 37 years [interquartile range (IQR), 29-48]; 231 women [58%]), 398 (99.5%) completed the trial. The median time to resolution of symptoms was 10 days (IQR, 9-13) in the ivermectin group compared with 12 days (IQR, 9-13) in the placebo group (hazard ratio for resolution of symptoms, 1.07 [95% CI, 0.87 to 1.32]; *P* = .53 by log-rank test). By day 21, 82% in the ivermectin group and 79% in the placebo group had resolved symptoms. The most common solicited adverse event was headache, reported by 104 patients (52%) given ivermectin and 111 (56%) who received placebo. The most common serious adverse event was multiorgan failure, occurring in 4 patients (2 in each group).

Conclusion and Relevance Among adults with mild COVID-19, a 5-day course of ivermectin, compared with placebo, did not significantly improve the time to resolution of symptoms. The findings do not support the use of ivermectin for treatment of mild COVID-19, although larger trials may be needed to understand the effects of ivermectin on other clinically relevant outcomes.

Research | Open Access | Published: 02 July 2021

Ivermectin to prevent hospitalizations in patients with COVID-19 (IVERCOR-COVID19) a randomized, double-blind, placebo-controlled trial

Julio Vallejos, Rodrigo Zoni, [...]María Gabriela Aguirre

BMC Infectious Diseases **21**, Article number: 635 (2021) | Cite this article

146k Accesses | **3679** Altmetric | Metrics

Results

The mean age was 42 years (SD ± 15.5) and the median time since symptom onset to the inclusion was 4 days [interquartile range 3–6]. The primary outcome of hospitalization was met in 14/250 (5.6%) individuals in ivermectin group and 21/251 (8.4%) in placebo group (odds ratio 0.65; 95% confidence interval, 0.32–1.31; $p = 0.227$). Time to hospitalization was not statistically different between groups. The mean time from study enrollment to invasive mechanical ventilatory support (MVS) was 5.25 days (SD ± 1.71) in ivermectin group and 10 days (SD ± 2) in placebo group, ($p = 0.019$). There were no statistically significant differences in the other secondary outcomes including polymerase chain reaction test negativity and safety outcomes.

Conclusion

Ivermectin had no significant effect on preventing hospitalization of patients with COVID-19. Patients who received ivermectin required invasive MVS earlier in their treatment. No significant differences were observed in any of the other secondary outcomes.

STEVE KIRSCH ASKED ED MILLS TO HAVE A PUBLIC DISCUSSION WITH ME

- We suggested Bret Weinstein – “not impartial enough”
- I suggested I would sit with him and whoever of his Ivory Tower friends he wants to discuss with
  - “No-one wants to do it. Pierre generates a negative response”

Evidence Based Medicine Lie #2

"Results from studies with 'high risks of bias' cannot be trusted"

- TENET OF MODERN PHARMA-CONTROLLED MEDICAL JOURNALS
  - "Low Quality," "Small," "Observational Trials" with "high risk of bias" are not evidence of efficacy"… and are not sufficiently robust to be published
- Harvey Risch, PhD:
  - Risks of bias, even if accurate, are not evidence of bias, nor estimates of actual bias.
  - Risks are subjective and scored according to epidemiologically irrational ad hoc principles.
  - **Their adjustment does not generally alter results** (Hartling et al., 2013; Bae, 2016)
  - They introduce random information that makes the observed adjusted results even more imprecise.