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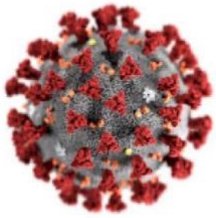

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CALTCM COVID-19 Webinar Series

October 18, 2021

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Webinar Planning Committee

Patricia Latham Bach, PsyD, RN
Heather D'Adamo, MD, CMD
Janice Hoffman-Simen, Pharm.D., EdD, APh, BCGP, FASCP
Ashkan Javaheri, MD
Albert Lam, MD
Dominic Lim, MPH
Anne-Marie Louissaint, LNHA, RCFE, MHA
Jay Luxenberg, MD
Tina Meyer, DHSc, MS, PA-C
Karl Steinberg, MD, CMD, HMDC
Michael Wasserman, MD, CMD

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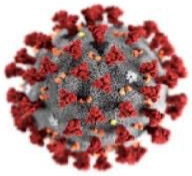

2021 Webinar Schedule

November 8
December 6

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Stephen R. Baddley
Director of Operations
Kalesta Healthcare Group

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Webinar Faculty

Jay Luxenberg, MD
Chief Medical Officer
On Lok

CALTCM, Wave Editor-in-Chief

San Francisco, CA

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Webinar Faculty

Ashkan Javaheri, MD, CMD

Geriatrician

Mercy Medical Group–Dignity Health Medical Foundation

Head of the Geriatric Division, Associate Clinical Professor, UC Davis School of Medicine

Sacramento, CA

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Webinar Faculty

Noah Marco, MD

Chief Medical Officer
Los Angeles Jewish Home

Executive Director
Brandman Research Institute

Medical Director, IPA LAJH Medical Associates

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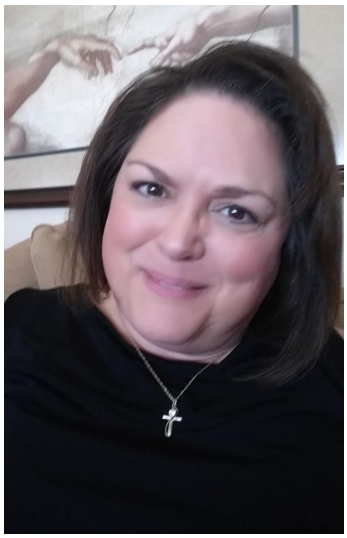

Webinar Moderator

Tina M. Meyer, DHSc, MS, PA-C

Associate Dean & Tenured Associate Professor

College of Health Sciences

Western University of Health Sciences

Pomona, CA

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New Developments in Treatment and Prevention

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Overview of the New Antiviral Treatment Options for COVID-19

Ashkan Javaheri, MD, CMD

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Molnupiravir

- Developed at Emory University initially to treat influenza, Ebola and various coronaviruses
- The drug was named after the hammer of Thor
  - Mjolnir
- Antiviral action: Introduction of copying errors during RNA replication
- In March 2020, researches started use molnupiravir to treat human cells infection with SARS-CoV2

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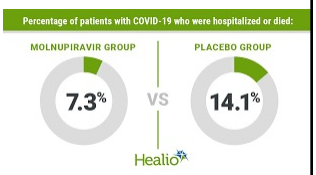
COVID-19: Molnupiravir reduces risk of hospital admission or death by 50% in patients at risk, MSD reports

MERCK



- Phase 3 MOVe-OUT trial
- 775 patients
- Enrollment Criteria
  - Non-hospitalized adult patient with mild-mod COVID-19 within 5 days
  - At lease one risk factor for poor outcome
    - Obesity, diabetes, heart disease, > 60 yrs
- 385 molnupiravir group- 28 (7.3%) hospitalized, 0 deaths
- 390 placebo group- 53 (14.1%) hospitalized, 8 deaths (first 28 days)
- Reduces the risk of hospital admission or death from COVID-19 by approximately 50%.

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nature

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NEWS | 08 October 2021 | Clarification 09 October 2021

How antiviral pill molnupiravir shot ahead in the COVID drug hunt

The Merck pill, which could become the first oral antiviral COVID treatment, forces the SARS-CoV-2 coronavirus to mutate itself to death.

- First pill to treat mild to mod disease unlike remdesivir and monoclonal antibodies
- Estimated cost $700 for a 5-day course
- Seeking EAU from FDA
  - https://www.nature.com/articles/d41586-021-02783-1

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Ivermectin

- Discovered in 1975
- William Campbell and Satoshi Omura won the 2015 Nobel Prize in Physiology and Medicine for its discovery and applications
- FDA approved for parasite infestations
  - Scabies, pediculosis, onchoverciasis (river blindness), strongyloidiasis
- Veterinary medicine
  - Heartworm and acariasis

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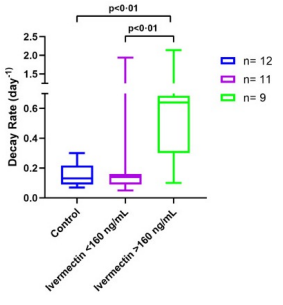
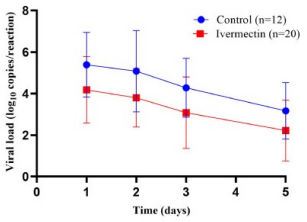
Antiviral Effect of High-dose Ivermectin in Adults with COVID-19: A Proof-of-Concept Randomized Trial

- 45 participants were recruited (30 to IVM and 15 controls)
- High-dose IVM 0·6 mg/kg/day for 5 days
- The viral decay rate in treated patients with IVM plasma levels >160 ng/mL was significantly greater (median 0·64 d^{-1}) compared to untreated controls
- No differences in clinical evolution at day-7 and day-30 between groups were observed.
- No significant difference in viral load





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

- 400 patients- RCT IVM 300 µg/kg of body weight per day for 5 days (n = 200) or placebo (n = 200)
- Median age 37 years
- Mild symptoms with positive PCR for 7-days or fewer
- The median time to resolution of symptoms was 10 days (IQR, 9-13) in the IVM group compared with 12 days
- By day 21, 82% in the IVM group and 79% in the placebo group had resolved symptoms.
- Ivermectin 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
  - JAMA. 2021;325(14):1426-1435. doi:10.1001/jama.2021.3071 Published online March 4, 2021.

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Does Ivermectin Have a Role in Managing COVID-19?

NEJM Journal Watch

- Ivermectin has some antiviral properties
- Several studies have reported clinical improvements with the ivermectin in COVID-19 patients
- Most clinical trials had small sample sizes.
- The dosages of ivermectin varied among studies and, in most, were markedly lower than required to achieve plasma levels mirroring the concentrations that enabled in vitro antiviral activity.
- Several of the randomized trials were open-label and unblinded.
- Many studies involved concomitant medications that could affect the analysis of ivermectin's safety and efficacy.
- Many studies did not have clear outcome measures and did not carefully assess COVID-19 severity.

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Ivermectin
More Rx More Poisoning

- Ivermectin dispensing from outpatient retail pharmacies in the U.S. increased from an average of 3,600 prescriptions per week at the pre-pandemic baseline to a peak of 39,000 prescriptions in the week ending Jan. 8, 2021.
- Ivermectin dispensing was on the rise again, rapidly increasing to more than 88,000 prescriptions in the week ending Aug. 13
- According to the CDC, this represents a 24-fold increase
- Ivermectin poisoning calls have increased by 163%, according to data collected by the American Association of Poison Control Centers

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Why You Should Not Use Ivermectin to Treat or Prevent COVID-19

- The FDA has not authorized or approved ivermectin for use in preventing or treating COVID-19 in humans or animals.
- Currently available data do not show ivermectin is effective against COVID-19.
- Clinical trials assessing ivermectin tablets for the prevention or treatment of COVID-19 in people are ongoing.
- Taking large doses of ivermectin is dangerous.
- Even the levels of ivermectin for approved human uses can interact with other medications, like blood-thinners.
- can cause nausea, vomiting, diarrhea, hypotension (low blood pressure), allergic reactions (itching and hives), dizziness, ataxia (problems with balance), seizures, coma and even death.
    - https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19

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Remdesivir

- Remdesivir is approved by the Food and Drug Administration (FDA) for the treatment of COVID-19 in hospitalized adult and pediatric patients (aged ≥12 years and weighing ≥40 kg).
- The safety and efficacy of combination therapy of remdesivir with corticosteroids have not been rigorously studied in clinical trials; however, there are theoretical reasons that combination therapy may be beneficial in some patients with severe COVID-19.
- Intravenous - 200 mg IV x1 then 100mg IV q24 h x 4 days for hospitalized patients not on mechanical vent or ECMO.

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NIH COVID-19 Treatment Guidelines

- NIH Clinical Guidelines for management of hospitalized adults with COVID-19

Figure 2. Therapeutic Management of Hospitalized Adults With COVID-19 Based on Disease Severity

DISEASE SEVERITY	PANEL'S RECOMMENDATIONS
Hospitalized but Does Not Require Supplemental Oxygen	The Panel **recommends against** the use of **dexamethasone (AIIa)** or **other corticosteroids (AIII)**.[a] There is insufficient evidence to recommend either for or against the routine use of remdesivir. For patients at high risk of disease progression, remdesivir may be appropriate.
Hospitalized and Requires Supplemental Oxygen	Use one of the following options: • **Remdesivir**[b] (e.g., for patients who require minimal supplemental oxygen) **(BIIa)** • **Dexamethasone plus remdesivir**[b] (e.g., for patients who require increasing amounts of supplemental oxygen) **(BIII)** • **Dexamethasone** (when combination with remdesivir cannot be used or is not available) **(BI)**
Hospitalized and Requires Oxygen Delivery Through a High-Flow Device or Noninvasive Ventilation	Use one of the following options: • **Dexamethasone (AI)** • **Dexamethasone plus remdesivir**[b] **(BIII)** For recently hospitalized[c] patients with rapidly increasing oxygen needs and systemic inflammation: • Add either **baricitinib (BIIa)** or **IV tocilizumab (BIIa)** to one of the two options above[d] • If neither baricitinib nor IV tocilizumab is available or feasible to use, **tofacitinib** can be used instead of baricitinib **(BIIa)** or **IV sarilumab** can be used instead of IV tocilizumab **(BIIa)**.
Hospitalized and Requires IMV or ECMO	• **Dexamethasone (AI)** For patients who are within 24 hours of admission to the ICU: • **Dexamethasone plus IV tocilizumab (BIIa)** • If IV tocilizumab is not available or not feasible to use, **IV sarilumab** can be used **(BIIa)**.

Rating of Recommendations: A = Strong; B = Moderate; C = Optional
Rating of Evidence: I = One or more randomized trials without major limitations; IIa = Other randomized trials or subgroup analyses of randomized trials; IIb = Nonrandomized trials or observational cohort studies; III = Expert opinion

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Lopinavir/ Ritonavir HIV Protease Inhibitors

- Lopinavir/ritonavir **did not show** efficacy in two large randomized controlled trials in hospitalized patients with COVID-19
- There is currently a lack of data on the use of lopinavir/ritonavir in nonhospitalized patients with COVID-19.
- The pharmacodynamics of lopinavir/ritonavir raise concerns about whether it is possible to achieve drug concentrations that can inhibit the SARS-CoV-2 proteases

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Nitazoxanide

NIH COVID-19 Treatment Guidelines

- Broad-spectrum thiazolide antiparasitic agent that is approved by the FDA for the treatment of *Cryptosporidium parvum* and *Giardia duodenalis* infections
- Has in vitro antiviral activity against a range of viruses
- Two randomized controlled trials that were conducted in Brazil and the United States did not find a significant clinical benefit for nitazoxanide treatment in nonhospitalized adults with COVID-19 when treatment was initiated within 2 to 5 days after illness onset
- Nitazoxanide is generally well tolerated.
- More well-designed, and well-conducted clinical trials are needed
    - https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/nitazoxanide/

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