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I-MASK+ PREVENTION & EARLY OUTPATIENT TREATMENT PROTOCOL FOR COVID-19

PREVENTION PROTOCOL (for Omicron/Delta variants)

ANTI-VIRALS & ANTISEPTICS

Ivermectin²

Chronic Prevention

0.2 mg/kg per dose (take with or after a meal) — twice a week for as long as disease risk is elevated in your community. Alternative: Hydroxychloroquine – 200 mg tablet daily.

Post COVID-19 Exposure Prevention³

0.4 mg/kg per dose (take with or after a meal) — one dose today, repeat after 48 hours. Alternative: Hydroxychloroquine – 400 mg twice day on day 1, then 200 mg twice a day on Days 2 and 3.

Gargle mouthwash

2 x daily – gargle (do not swallow) antiseptic mouthwash with cetylpyridinium chloride (e.g. Scope[™], Act[™], Crest[™]), 1% povidone/iodine solution or Listerine[™] with essential oils.

IMMUNE FORTIFYING / SUPPORTIVE THERAPY

Vitamin D3	Optimal approach to dosing requires testing of 25(OH)D level. For dosing guidance, see Table 1 if level is known and Table 2 if level is unknown.
Vitamin C	500–1,000 mg 2 x daily
Quercetin	250 mg/day
Zinc	30–40 mg/day (elemental zinc)
Melatonin	6 mg before bedtime (causes drowsiness)

IVERMECTIN ALTERNATIVE

Nigella Sativa 40 mg/kg daily ⁴ (black cumin seed)

To be used if ivermectin not available or added to ivermectin for optimal prevention.

EARLY TREATMENT PROTOCOL \rightarrow see page 2

Supporting information

Questions regarding the multiple additions to the I-MASK+ protocol for the Delta variant can be found in our Frequently Asked Questions page <u>flccc.net/new-i-mask-faqs</u>. Here you will find answers to the the critical role of anti-androgen therapy, the <u>safety and need for higher dosing of ivermectin</u>, and guidance on the number of components of the protocol that should be used in the treatment of an individual patient.

Efficacy of Ivermectin

Ivermectin is a medication uniquely suited to treat COVID-19 given its now well-described, potent anti-viral and anti-inflammatory properties.

The efficacy of ivermectin is supported by results from 64 controlled trials, 32 of them randomized, and 16 of those were double-blinded, the gold standard of research design. A summary (meta-analysis) of these trials find statistically significant reductions in transmission, time to recovery, hospitalization, and death.

The most up-to-date summary of the totality of the supportive evidence for ivermectin in COVID-19 can be found here: flccc.net/flccc-summary-of-the-evidence-of-ivermectin-in-covid-19

Finally, in a historic achievement of public health, as of September 16, 2021, the North Indian state of Uttar Pradesh has effectively eradicated COVID from its population of 241 million people after widely distributing ivermectin in their treatment and prevention protocols for COVID-19. Please see also <u>The Latest Results of Ivermectin's Success in</u> <u>Treating Outbreaks of COVID-19</u>.

For an overview of the developments in prevention and treatment of COVID-19, please visit flccc.net/covid-19-protocols.

Please check our homepage regularly for updates of our COVID-19 Protocols! — New medications may be added and/or dose changes to existing medications may be made as further scientific studies emerge.



CONSULT HEALTH CARE PROVIDER

Discuss all protocol elements as well as the role of vaccination.¹



WEAR MASKS

Wear a cloth, surgical, or N95 mask when in confined, poorly ventilated, crowded indoor spaces with non-household members.



KEEP DISTANCE

Until the end of the COVID-19 crisis, we recommend keeping a minimum distance of approx. 2 m/6 feet in public from people who are not from your own household.



WASH HANDS

We recommend, after a stay during and after outings from home (shopping, subway etc.), a thorough hand cleaning (20–30 sec. with soap), or also to use a hand disinfectant in between.



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EARLY TREATMENT PROTOCOL⁵ (for Omicron/Delta variants)

1. First line agents (use any or all medicines; listed in order of priority/importance)

ANTI-VIRALS

Ivermectin²: 0.4–0.6 mg/kg per dose (take with or after a meal) — one dose daily, take for 5 days or until recovered. Use upper dose if: 1) in regions with aggressive variants (e.g. Delta); 2) treatment started on or after day 5 of symptoms or in pulmonary phase; or 3) multiple comorbidities/risk factors.

and/or Hydroxychloroquine (preferred for Omicron): 200 mg PO twice daily; take for 5 days or until recovered.

ANTI-SEPTIC ANTI-VIRALS

Antiviral mouthwash: Gargle 3 x daily (do not swallow; must contain chlorhexidine, povidone-iodine, or cetylpyridinium chloride). Iodine nasal spray/drops: Use 1% povidone-iodine commercial product as per instructions 2–3 x daily. If 1%-product not available, must first dilute the more widely available 10%-solution⁶ and apply 4–5 drops to each nostril every 4 hours. (No more than 5 days in pregnancy.)

ANTI-COAG	ULANTS / IMMUNE FORTIFYING	SYNERGISTIC THERAPIES	
Aspirin	325 mg daily (unless contraindicated)	Quercetin	250 mg 2 x daily
Vitamin D3 Melatonin	Optimal approach to dosing requires testing of 25(OH)D level. For dosing guidance, see Table 1 if level is known and Table 2 if level is unknown. 10 mg before bedtime (causes drowsiness)	Zinc Vitamin C	100 mg/day (elemental zinc) 500–1,000 mg 2 x d
NUTRITION	AL THERAPEUTICS (for 14 days) ⁴	PULSE OX	IMETER

Curcumin (turmeric) Nigella Sativa (black cumin seed) Honey

500 mg 2 x daily 80 mg/kg daily 1 gram/kg daily

2. Second line agents (listed in order of priority/importance)

Add to first line therapies above if: 1) ≥ 5 days of symptoms; 2) Poor response to therapies above; 3) Significant comorbidities.

DUAL ANTI-ANDROGEN THERAPY

- 1. **Spironolactone** 100 mg 2 x daily for ten days.
- 2. Dutasteride 2 mg on day 1, followed by 1 mg daily for 10 days. If Dutasteride not available, use Finasteride 10 mg daily for 10 days.

FLUVOXAMINE

50 mg 2 x daily for 10 days7

Consider Fluoxetine 30 mg daily for 10 days as an alternative (it is often better tolerated). Avoid if patient is already on an SSRI.

MONOCLONAL ANTIBODY THERAPY

Sotrovimab⁸

500 mg each in a single intravenous infusion. Antibody therapy is for patients within 5 days of first symptoms, non-severe symptoms, and one or more risk factors as: Age>55y; BMI>25; pregnancy; chronic lung, heart, or kidney disease; diabetes.

Trials data supporting sotrovimab against Omicron are not available, however the manufacturer has claimed it retains neutralizing capability against this variant.

daily

Monitoring of oxygen saturation is recommended (for instructions see page 4)

3. Third line agent

If below criteria are met, consider

CORTICOSTEROIDS

Prednisone or Methylprednisolone

1 mg/kg daily for 5 days followed by slow taper or escalation according to patient response.

Criteria:

After day 7–10 from first symptoms and patient has either: abnormal chest x-ray. shortness of breath, or oxygen saturations of 88-94%.

If oxygen saturation is lower than 88%, emergency room evaluation should be sought.

Notes

1 As global COVID-19 cases continue to rise even in the most vaccinated populations, the need for effective prevention and early treatment has never been more critical. Vaccines have shown some efficacy in preventing the most severe outcomes of COVID-19 however, rising vaccine breakthrough infection rates do not support the rationale for mandates. Instead. vaccines are part of a multi-modal COVID-19 strategy and we encourage health authorities to allow doctors to use all tools at their disposal. These include prevention and early treatment protocols using approved, safe and effective medications and supplements to safeguard the health of patients. Any decision on medical treatment, including vaccines, should be made in consultation with a health care provider.

2 The dosing may be updated as further scientific studies emerge. The safety of ivermectin in pregnancy has not been definitively established. Use in the 1st trimester should be discussed with vour doctor.

3 To use if a household member is COVID-19 positive, or you have prolonged exposure to a COV-ID-19 positive patient without wearing a mask.

4 For more information on nutritional therapeutics and how they can help with COVID-19 please see: flccc.net/covid-19-protocols/nutritional-therapeutics

5 For late phase – hospitalized patients - see the FLCCC's "MATH+ Hospital Treatment Protocol for COVID-19" on www. flccc.net

6 To make 1% povidone/iodine concentrated solution from 10% povidone/iodine solution, it must be diluted first.

One dilution method is as follows:

- First pour 1½ tablespoons (25 ml) of 10% povidone/ iodine solution into a nasal irrigation bottle of 250 ml.
- Then fill to top with distilled. sterile or previously boiled water.
- Tilt head back, apply 4–5 drops to each nostril. Keep tilted for a few minutes. let drain.

7 Some individuals who are prescribed fluvoxamine experience acute anxiety which needs to be carefully monitored for and treated by the prescribing clinician to prevent rare escalation to suicidal or violent behavior.

8 This medication requires an infusion center. To find the nearest location in the U.S., visit www.infusioncenter.org or call for eligibility and location 1-877-332-6585 for English and 1-877-366-0310 for Spanish.



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Tables

Table 1. Guidance on upfront loading dose regimens to replenish Vitamin D stores in the body

Achieving serum 25(OH)D concentrations above 50 ng/mL based on serum 25(OH)D concentration in non-emergency situations in a 70 kg adult *				
Serum vitamin D (ng/mL)**	Vitamin D dose, 50,000 IU capsules: Initial and weekly ***		Duration	Total amount for deficit
	Initial Dose (IU)	Weekly dose (50,000 IU caps)	(weeks)	correction (IU, in millions) ****
< 10	300,000	х З	8-10	1.5 – 1.8
11–15	200,000	x 2	8-10	1.0 - 1.2
16–20	200,000	x 2	6 – 8	0.8 - 1.0
21–30	100,000	x 2	4 - 6	0.5 - 0.7
31–40	100,000	x 2	2 – 4	0.3 – 0.5
41–50	100,000	x 1	2 – 4	0.2 - 0.3

* A suitable daily or weekly maintenance dose should start after completing the schedule.

** For conversion of ng/mL to nmol/L, multiply by 2.5.

*** Mentioned replacement doses can be taken as single cumulative doses or spread out through the week.

**** Estimated deficit of vitamin D needed to replenish body stores.

(Table adapted with permission from S.J. Wimalawansa)

Table 2. Vitamin D dosing in the absence of a baseline Vitamin D level

Longer-term maintenance of serum 25(OH)D concentrations above 50 ng/mL based on body weight *				
	Dose (IU) kg/day	Dose (IU)/day		
Body-weight category		Daily dose (IU)	Once a week	
BMI ≤ 19 (under-weight)	40 - 70	$\simeq 2,000 - 4,000$	~ 25,000	
BMI 20–29 (non-obese person)	70 - 100	≈ 5,000 - 7,000	~ 50,000	
BMI 30–39 (obese persons)	100 - 150	≈ 9,000 - 15,000	~ 75,000	
BMI ≥ 40 (morbidly obese persons)	150 - 200	≃ 16,000 - 30,000	~ 100,000	

(Table adapted with permission from S.J. Wimalawansa)

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FRONT LINE COVID-19 CRITICAL CARE ALLIANCE PREVENTION & TREATMENT PROTOCOLS FOR COVID-19

I-MASK+ PREVENTION & EARLY OUTPATIENT TREATMENT PROTOCOL FOR COVID-19

Additional information

Pulse Oximeter (usage instructions)

In symptomatic patients, monitoring with home pulse oximetry is recommended (due to asymptomatic hypoxia). The limitations of home pulse oximeters should be recognized, and validated devices are preferred. Multiple readings should be taken over the course of the day, and a downward trend should be regarded as ominous. Baseline or ambulatory desaturation < 94% should prompt hospital admission. The following guidance is suggested:

Calculation for ivermectin dose (0.2 mg per kg)

Body weight Conversion: 1 kg ≈ 2.2 lbs (doses calculated per upper end of weight range)		(Each table	Dose .2 mg/kg ≈ 0.09 mg/lb t = 3 mg; doses rounded earest half tablet above)
70–90 lb	32–40 kg	8 mg	(3 tablets = 9 mg)
91–110 lb	41–50 kg	10 mg	(3.5 tablets)
111–130 lb	51–59 kg	12 mg	(4 tablets)
131–150 lb	60–68 kg	13.5 mg	(4.5 tablets)
151–170 lb	69–77 kg	15 mg	(5 tablets)
171–190 lb	78–86 kg	16 mg	(5.5 tablets)
191–210 lb	87–95 kg	18 mg	(6 tablets)
211–230 lb	96–104 kg	20 mg	(7 tablets = 21 mg)
231–250 lb	105–113 kg	22 mg	(7.5 tablets=22.5 mg)
251–270 lb	114–122 kg	24 mg	(8 tablets)
271–290 lb	123–131 kg	26 mg	(9 tablets = 27 mg)
291–310 lb	132–140 kg	28 mg	(9.5 tablets=28.5 mg)

- Use the index or middle finger; avoid the toes or ear lobe.
- Only accept values associated with a strong pulse signal.
- Observe readings for 30–60 seconds to identify the most common value.

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- Remove nail polish from the finger on which measurements are made.
- Warm cold extremities prior to measurement.

For higher doses used in our I-MASK+ Protocol please multiply the value found in the table for 0.2 mg/kg, e.g.:

- 0.4 mg/kg: double the 0.2 mg/kg dose
- **0.6 mg/kg:** triple the 0.2 mg/kg dose

Tablets can be halved for more accurate dosing. Then round to nearest half tablet above.

Note that Ivermectin is available in different tablet strengths (e.g. with 3, 5 or 6 mg) and administration forms (tablets, drops) depending on the country (please refer to the package information).

In our table we calculate doses using 3 mg tablets (the most common dose per tablet in the U.S.).

If your tablets contain a different amount of ivermectin than 3 mg, you must calculate the number of tablets to equal the dose of ivermectin required.

Disclaimer

The "I-MASK+ Prevention & Early Outpatient Treatment Protocol for COVID-19" is solely for educational purposes regarding potentially beneficial therapies for COVID-19. <u>Never disregard professional medical advice because of something you have read on our website and releases</u>. This protocol is not intended to be a substitute for professional medical advice, diagnosis, or treatment in regards to any patient. Treatment for an individual patient should rely on the judgement of your physician or other qualified health provider. Always seek their advice with any questions you may have regarding your health or medical condition. Please note our full disclaimer at: www.flccc.net/disclaimer

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