

I-RECOVERSM

POST-VACCINE TREATMENT PROTOCOL

Management of Post-Vaccine Syndrome

Major public health authorities do not recognize post-COVID-vaccine injuries; and there is no specific ICD classification code for this disease. However, while no official definition exists, a temporal correlation between receiving a COVID-19 vaccine and beginning or worsening of a patient's clinical manifestations is sufficient to diagnose as a COVID-19 vaccine-induced injury, when the symptoms are unexplained by other concurrent causes.

Since there are no published reports detailing the management of vaccine-injured patients, our treatment approach is based on the postulated pathogenetic mechanism, clinical observation, and patient anecdotes. Treatment must be individualized according to each patient's presenting symptoms and disease syndromes. It is likely that not all patients will respond equally to the same intervention; a particular intervention may be life-saving for one patient and totally ineffective for another.

Early treatment is essential; it is likely that the response to treatment will be attenuated when treatment is delayed.

FIRST LINE THERAPIES

Not symptom specific; listed in order of importance.

- **Intermittent daily fasting** or periodic daily fasts.

Fasting has a profound effect on promoting immune system homeostasis, partly by stimulating the removal of damaged cells (autophagy) and mitochondria (mitophagy) and clearing misfolded and foreign proteins. Intermittent fasting and autophagy likely have an important role in promoting the breakdown and elimination of the spike protein. Fasting is contraindicated in patients under 18 (impairs growth) and during pregnancy and breastfeeding. Patients with diabetes, as well as those with serious underlying medical conditions, should consult their primary care provider prior to fasting, as changes in their medications may be required and these patients require close monitoring. Hydroxychloroquine may limit the benefit of intermittent fasting. See page 3 for tips on fasting.

- **Spermidine; (follow instructions on product) and/or Resveratrol; (500mg twice daily).**

Spermidine, a naturally occurring polyamine, and resveratrol, a naturally occurring phytochemical, have been shown to promote autophagy. Wheatgerm, mushrooms, grapefruit, apples and mango are high natural sources of spermidine.

- **Ivermectin:** 0.2–0.3 mg/kg, daily for up to 4–6 weeks.

Ivermectin has potent anti-inflammatory properties. It also binds to the spike protein, aiding in the elimination by the host. It is likely that ivermectin and intermittent fasting act synergistically to rid the body of the spike protein. Ivermectin is best taken with or just following a meal for greater absorption. A trial of ivermectin should be considered as first line therapy. It appears that patients can be grouped into two categories: i) ivermectin responders and ii) ivermectin non-responders. This distinction is important, as the latter are more difficult to treat and require more aggressive therapy. Due to the possible drug interaction between quercetin and ivermectin, these drugs should not be taken simultaneously (i.e., should be staggered morning and night).

- **Low dose naltrexone (LDN):** Begin with 1 mg/day and increase to 4.5 mg/day, as required. May take 2 to 3 months to see full effect.

LDN has been demonstrated to have anti-inflammatory, analgesic and neuromodulating properties.

- **Melatonin:** 2–6 mg *slow release/extended release* prior to bedtime.

Melatonin has anti-inflammatory and antioxidant properties and is a powerful regulator of mitochondrial function. The dose should be started at 750 mcg (µg) to 1 mg at night and increased as tolerated. Patients who are slow metabolizers may have very unpleasant and vivid dreams with higher doses.

- **Aspirin:** 81 mg/day.

- **Vitamin C:** 1000 mg orally three to four times a day.

Vitamin C has important anti-inflammatory, antioxidant, and immune-enhancing properties, including increased synthesis of type I interferons. Avoid in patients with a history of kidney stones. Oral Vitamin C helps promote growth of protective bacterial populations in the microbiome.

- **Vitamin D and Vitamin K2:** A dose of 4000–5000 units/day of Vitamin D, together with Vitamin K2 100 mcg/day is a reasonable starting dose.

The dose of Vitamin D should be adjusted according to the baseline Vitamin D level.

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About this Protocol

This document is primarily intended to assist health-care professionals in providing appropriate medical care for vaccine-injured patients. Patients should always consult their health-care provider before embarking on any new treatment.

Patients with post-vaccine syndrome must not receive further COVID-19 vaccines of any type. Likewise, patients with long COVID should avoid all COVID vaccinations.

Note that there are significant overlaps between the symptoms and features of long COVID and post-vaccine syndrome. However, a number of clinical features appear to be characteristic of post-vaccine syndrome; most notably, severe neurological symptoms appear to be more common following vaccination.

Please check our website at flccc.net/covid-19-protocols for updates to our COVID-19 protocols. New medications may be added and/or changes may be made to doses of existing medications as further evidence emerges.

For more information on nutritional therapeutics and how they can help with COVID-19, visit geni.us/COVID_nutrition

For Additional Potential Treatments, Disease-Specific Therapeutic Adjuncts, and References please see the complete guide, "An Approach to the Management of Post-Vaccine Syndrome," available at flccc.net/covid-19-protocols/i-recover-post-vaccine-treatment

FIRST LINE THERAPIES (continued from page 1)

- ***Nigella sativa* encapsulated oil:** 200–500 mg twice daily.
It should be noted that thymoquinone (the active ingredient of *Nigella sativa*) decreases the absorption of cyclosporine and phenytoin. Patients taking these drugs should, therefore, avoid taking *Nigella sativa*. Furthermore, two cases of serotonin syndrome have been reported in patients taking *Nigella sativa* who underwent general anaesthesia (probable interaction with opiates).
- **Probiotics/prebiotics.**
Patients with post-vaccine syndrome classically have a severe dysbiosis with loss of Bifidobacterium. Kefir is a highly recommended nutritional supplement high in probiotics. Suggested probiotics include Megasporebiotic (Microbiome labs), TrueBifidoPro (US Enzymes) and yourgutplus+.
- **Magnesium:** 500 mg/day.
- **Omega-3 fatty acids:** Vascepa, Lovaza or DHA/EPA; 4 g/day.
Omega-3 fatty acids play an important role in the resolution of inflammation by inducing resolvin production.

ADJUNCTIVE/SECOND LINE THERAPIES

Listed in order of importance.

- **Hydroxychloroquine (HCQ):** 200 mg twice daily for 1–2 weeks, then reduce as tolerated to 200 mg/day.
HCQ is the preferred second line agent. HCQ is a potent immunomodulating agent, and is considered the drug of choice for systemic lupus erythematosus (SLE), where it has been demonstrated to reduce mortality from this disease. Thus, in patients with positive autoantibodies or where autoimmunity is suspected to be a prominent underlying mechanism, HCQ should be considered earlier. Further, it should be noted that SLE and post-vaccine syndrome have many features in common. HCQ is safe in pregnancy; indeed, this drug has been used to treat preeclampsia. With long term usage, the dose should be reduced (100 or 150 mg/day) in patients weighing less than 61 kg (135 lbs).
- **“Mitochondrial energy optimizer”** with pyrroloquinoline quinone (e.g., Life Extension Energy Optimizer or ATP 360®).
- **Non-invasive brain stimulation (NIBS):**
NIBS using transcranial direct current stimulation or transcranial magnetic stimulation has been demonstrated to improve cognitive function in patients with long COVID as well as other neurological diseases. NIBS is painless, extremely safe, and easy to administer. It is a recognized therapy offered by many Physical Medicine and Rehabilitation Centers. Patients may also purchase an FDA-approved device for home use.
- **N-acetyl cysteine (NAC):** 600–1500 mg/day.
- **Intravenous Vitamin C:** 25 g weekly, together with oral Vitamin C 1000 mg (1 gram) 2–3 times per day.
High dose IV vitamin C is “caustic” to the veins and should be given slowly over 2–4 hours. Furthermore, to assess patient tolerability the initial dose should be between 7.5–15 g. Total daily doses of 8–12 g have been well-tolerated, however chronic high doses have been associated with the development of kidney stones, so the duration of therapy should be limited. Wean IV Vitamin C as tolerated.
- **Quercetin:** 250-500 mg/day (or mixed flavonoids).
Flavonoids have broad spectrum anti-inflammatory properties, inhibit mast cells, and have been demonstrated to reduce neuroinflammation. Due to a possible drug interaction between quercetin and ivermectin, these drugs should not be taken simultaneously (i.e., should be staggered morning and night). The use of quercetin has rarely been associated with hypothyroidism. The clinical impact of this association may be limited to those individuals with pre-existent thyroid disease or those with subclinical thyroidism. Quercetin should be used with caution in patients with hypothyroidism and TSH levels should be monitored.
- **Fluvoxamine:** 50 mg twice daily. Start on a low dose of 12.5 mg/day and increase slowly as tolerated.
- **Low dose corticosteroid:** 10–15 mg/day prednisone for 3 weeks. Taper to 10 mg/day and then 5 mg/day, as tolerated.
- **Behavioral modification, mindfulness therapy, and psychological support.**
May help improve patients overall well-being and mental health. Suicide is a real problem in the vaccine-injured patient. Support groups and consultation with mental health professionals are important.
- **Tai Chi and Yoga.**
Tai Chi, a health-promoting form of traditional Chinese martial art, has shown to be beneficial for preventing and treating diseases including long COVID. Yoga has immunomodulating properties that may be beneficial in vaccine-injured patients. It should be noted that long COVID is characterized by severe post-exertional fatigue and/or worsening of symptoms, therefore patients should be counseled to moderate exertion, increasing slowly only as tolerated.

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Disclaimer

The I-RECOVER: Post-Vaccine Treatment Protocol is meant solely for educational purposes regarding potentially beneficial treatment approaches for post-vaccine syndrome.

Never disregard professional medical advice because of something you have read on our website and releases. This is not intended to be a substitute for professional medical advice, diagnosis, or treatment regarding any patient.

Treatment for an individual patient is determined by many factors and thus should rely on the judgment of your physician or qualified healthcare provider. Always seek their advice with any questions you may have regarding your medical condition or health.

Please note our full disclaimer at:
www.flccc.net/disclaimer

Contributors

This protocol was a collaborative effort drawing on the expertise of a dozen world-renowned physicians. We are also extremely grateful for the feedback of the many vaccine-injured people who shared their experiences with us.

THIRD LINE THERAPIES (continued from page 2)

■ **Hyperbaric oxygen therapy (HBOT).**

HBOT has potent anti-inflammatory properties, decreasing pro-inflammatory cytokines while increasing IL-10. Furthermore, HBOT polarizes macrophages toward the M2 phenotype and improves mitochondrial function. Surprisingly, it is the increased pressure, rather than the increase in the concentration of dissolved oxygen, that appears to mediate these effects. HBOT is delivered at varying pressures, both with and without oxygen. The addition of oxygen increases the clinical response. Maximal clinical response is achieved via use of high-pressure chambers (typically reaching 2.4 ATM) with 100% oxygen for 60 minutes. If HBOT is delivered using lower pressure chambers (less than 1.5 ATM) without supplemental oxygen, the clinical response, although present, is significantly less such that a higher number of sessions will be needed to reach a clinical plateau. While there is very limited published data on the treatment of long COVID and post-vaccine syndrome, remarkable life-saving benefits have been reported anecdotally. The duration of treatment should be based on clinical response and continue until the benefit has plateaued. If no benefit is evident clinically after 10 sessions, then HBOT should be considered a therapeutic failure. This therapy is limited by logistical issues and cost.

■ **Low Magnitude Mechanical Stimulation (LMMS or whole body vibration therapy).**

Low-magnitude (0.3-0.4G), high-frequency (32-40 Hz) mechanical stimulation has been demonstrated to increase bone density as well as indices of general well-being in patients with a variety of medical disorders. It is postulated that this intervention recruits bone marrow stem cells in addition to having metabolic and immunologic effects. In humans, low-magnitude acceleration is applied through the feet, by standing on a platform oscillating at relatively high frequency. This is a very safe, painless and easy therapy to administer. Similar to noninvasive brain stimulation (NIBS) this therapy is offered by Physical Medicine and Rehabilitation Centers or a device may be purchased for home use.

OTHER POTENTIAL TREATMENTS

■ **Plasmapheresis**

Improves systemic cytokine levels, coagulopathy, and immune responsiveness in patients with severe COVID with a potential mortality benefit. However, is a limited and expensive resource that is not without complications. Durability of clinical response needs to be determined. While a therapeutic option for the severely neurologically impaired patient following vaccination, additional data is required before this modality can be widely recommended.

■ **Pentoxifylline (PTX); PTX ER, 400 mg three times daily, for patients with severe microcirculatory disturbances.**

A non-selective phosphodiesterase drug with anti-inflammatory and antioxidant effects. Improves red blood cell deformability and reduces blood viscosity, so can mitigate the hyper-viscosity and RBCs hyper-aggregation, linked with the development of coagulopathy in the vaccine-injured.

■ **Maraviroc; 300 mg orally twice daily.**

A C-C chemokine receptor type 5 (CCR5) antagonist. If 6 to 8 weeks have elapsed and significant symptoms persist despite above therapies, Maraviroc can be considered. Can be expensive and has risk for significant side effects and drug interactions. While many long COVID and post-vaccine patients have been treated this drug, its role requires further evaluation.

■ **Valproic acid; Depakote, 250mg 2-3 times daily.**

Has anti-inflammatory effects and polarizes macrophages towards a M2 phenotype. HDAC inhibitors are being studied for neural regeneration. Has important anticoagulant and anti-platelet effects. May be helpful for neurological symptoms.

■ **Sildenafil with or without L-arginine-L-Citrulline.**

Sildenafil doses titrated up from 25 to 100 mg 2-3 times daily with L-arginine/L-citrulline 5000 mg powder twice daily. May be helpful for brain fog as well as microvascular disease with clotting and poor perfusion. Note that curcumin, resveratrol, EGGG and valproic acid all potentiate phosphodiesterase 5 (PDE5) inhibitors.

■ **Sulforaphane (broccoli sprout powder) 500 mcg – 1g twice a day.**

While sulforaphane has many potential benefits in patients with COVID, long COVID and post-vaccine syndrome, there is limited clinical data to support it. We recommend a 100% whole broccoli sprout powder containing glucoraphanin and myrosinase.

■ **Dandelion (*Taraxacum officinale*).**

Root, flower and leaves contain an array of phytochemicals with anti-inflammatory, antioxidant, hypolipidemic, antimicrobial and anticoagulant properties. Widely reported to be effective for 'detoxifying' spike protein, however remains unclear whether dandelion extract actually binds to spike protein.

■ **VEDICINALS[®] 9.**

Unique phytopharmaceutical-based therapeutic suspension consisting of 9 bioactive compounds with antiviral, anti-inflammatory, immune modulatory, anti-pyretic and analgesic properties. A number of these compounds are included in our protocol and the additional benefit of this combination over more widely available flavanoid combinations is unknown.

■ **Carbon 60 (C60) or C60 fullerenes.**

Composed of 60 carbon atoms forming something that looks like a hollow soccer ball and considered as a "free radical sponge." Considered the single-most powerful antioxidant ever discovered.

■ **Cold Hydrotherapy (e.g. cold showers).**

Avoid warm/hot water baths.

Tips for Intermittent Fasting

Consult a trusted health-care provider or nutrition specialist before adopting any diet changes.

As the goal is to adopt fasting as a healthy life-style choice, it is important to make changes slowly (i.e., one month at a time) to increase success and allow your body time to adapt.

Always make quality food choices when planning meals.

Be sure to: stay hydrated; limit refined sugars; eat protein rich, good quality foods; maintain balance in your daily activities.

Two popular approaches include: time-restricted and caloric fasting.

For time-restricted fasting, start with an 11-hour eating window 5 days a week and gradually reduce to an 8-hour eating window 7 days a week.

For caloric fasting, eat normally 5 days a week and fast the other 2 days. On fasting days, restrict caloric intake to 500 kcal for women and 600 kcal for men. Build up gradually, by restricting caloric intake to 1000 kcal 1 day a week in the beginning.