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 a patient receiving a COVID-19 vaccine and beginning or worsening of 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

- Intermittent daily fasting or periodic daily fasts. Fasting has a profound effect on promoting immune system homeostasis, partly by stimulating autophagy and clearing misfolded and foreign proteins, promoting mitophagy and improving mitochondrial health, as well as increasing stem cell production. Intermittent fasting likely has an important role in promoting the breakdown and elimination of the spike protein.

- **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. 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 group are more difficult to treat and require more aggressive therapy.

- **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.

- **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 hyperthyroidism. 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 hyperthyroidism and TSH levels should be monitored.

About this Protocol

This document is primarily intended to assist healthcare professionals in providing appropriate medical care for vaccine-injured patients. Patients should always consult their healthcare 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/long-hauler syndrome 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
Tai Chi is a health-promoting form of traditional Chinese martial art, shown to be beneficial for preventing and treating diseases including long COVID. It should be noted that long COVID is characterized by severe post-exertional fatigue and/or worsening of symptomology, therefore patients should be counseled to moderate exertion, increasing slowly only as tolerated.

**Disorder of the immune system:**

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) and TrueBifidoPro (US Enzymes). Nigella Sativa: 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).

**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).

**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. Wear IV Vitamin C as tolerated.

**Fluvoxamine:** Start on a low dose of 12.5 mg/day and increase slowly as tolerated.

**“Mitochondrial energy optimizer”** with pyrroloquinoline quinone (e.g., Life Extension Energy Optimizer or ATP 360®).

**N-acetyl cysteine (NAC):** 600–1500 mg/day.

**Sulforaphane (broccoli extract):** 400 mcg/day.

**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 is important.

**Tai Chi.** Tai Chi is a health-promoting form of traditional Chinese martial art, shown to be beneficial for preventing and treating diseases including long COVID. It should be noted that long COVID is characterized by severe post-exertional fatigue and/or worsening of symptomology, therefore patients should be counseled to moderate exertion, increasing slowly only as tolerated.

**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. While the optimal dose and dosing schedule is unclear, a pressure of between 1.5 and 2.0 ATM appears to be necessary to mediate the anti-inflammatory effects; however, others have reported improvements with a little as 1.3 ATM. Pressures above 1.3 ATM can only be achieved using hard shell chambers. 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. This therapy is limited by logistical issues and cost.