I-RECOVER℠

POST-VACCINE TREATMENT PROTOCOL

Management of Post-Vaccine Syndrome

Major public health authorities do not recognize post-COVID-vaccine injuries and no official definition exists. However, a temporal correlation between receiving a COVID-19 vaccine and the beginning or worsening of a patient's clinical manifestations is sufficient to diagnose a COVID-19 vaccine-induced injury, when symptoms are otherwise unexplained by concurrent causes.

Since there are no published reports detailing how to manage 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. Chances are, not all patients will respond equally to the same intervention; a particular intervention may be life-saving for one patient and completely ineffective for another.

Early treatment is essential; the response to treatment will most likely 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 stimulates the clearing of damaged cells (autophagy), damaged mitochondria (mitophagy), and misfolded and foreign proteins. Fasting is contraindicated in patients younger than 18 (impairs growth), malnourished patients (BMI < 20 kg/m2), and during pregnancy and breastfeeding. Patients with diabetes, gout, or serious underlying medical conditions should consult their primary care provider before beginning fasting, as changes in medications may be required and these patients require close monitoring.

  Several studies have suggested that intermittent fasting may not be as beneficial for pre-menopausal women as it is for men. To reduce any adverse effects, women should take a mild approach to fasting: shorter fasts and fewer fasting days. We would suggest beginning a program of time-restricted eating consisting of fasting for 12 hours for two to three days a week (see Figure 1) and increasing from there. Furthermore, the fasting window should begin at least 4 hours before going to sleep. See sidebar for more tips on fasting. For more detailed information see 'An Approach to the Management of Post-Vaccine Syndrome'.

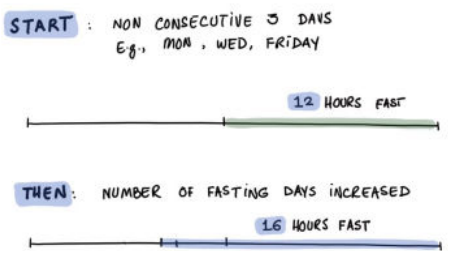

Figure 1. An Intermittent Fasting Plan for Pre-Menopausal Women

- **Ivermectin;** 0.2–0.3 mg/kg/day.

  Ivermectin, which has potent anti-inflammatory properties, binds to the spike protein and aids in its elimination. It is likely that ivermectin and intermittent fasting act synergistically to rid the body of spike protein. Ivermectin is best taken with or just following a meal for greater absorption. A trial of ivermectin should be included in the first-line treatment approach. The duration of treatment is determined by the clinical response. In patients with a suboptimal response, a trial of a higher dose (0.6 mg/kg/day) can be considered. If no improvement is noted after 4-6 weeks, the drug should be stopped. 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). The safety of ivermectin in pregnancy is uncertain, therefore this drug should be avoided in the first trimester of pregnancy.

- **Moderating physical activity**

  Patients with long COVID and post-vaccine symptoms frequently suffer from severe post-exertional fatigue and/or worsening of symptoms with exercise. Aerobic exercise is reported to be one of the worst therapeutic interventions for these patients. We recommend moderating activity to tolerable levels that do not worsen symptoms, keeping the patient's heart rate under 110 BPM. Furthermore, patients need to identify the activity level beyond which their symptoms worsen, and then aim to stay below that level of activity. Stretching and low-level resistance exercises are preferred over aerobic exercises.

- **Low dose naltrexone (LDN);** 1-4.5mg/day.

  LDN has been demonstrated to have anti-inflammatory, analgesic, and neuromodulating properties. Begin with 1 mg/day and increase to 4.5 mg/day, as required. May take 2 to 3 months to see full effect.

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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/treatment-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".

FIRST LINE THERAPIES

(continued from page 1)

- **Resveratrol;** 400-500 mg/day.
  This plant phytochemical (flavonoid) has remarkable biological properties and activates autophagy. A bio-enhanced formulation containing trans-resveratrol from Japanese Knotweed Root appears to have improved bioavailability. Quercetin acts synergistically and increases the bioavailability of resveratrol. Pterostilbene is another plant flavonoid similar to resveratrol, but with greater absorption and cellular uptake. A "high quality" combination supplement with resveratrol, quercetin, and pterostilbene is ideal. Resveratrol in a dose of 500 mg twice daily is suggested for acutely symptomatic patients. In recovered patients and those on preventative/maintenance therapy, a daily dose of 400-500 mg should suffice. The safety of these phytochemicals has not been determined in pregnancy and they should therefore be avoided. 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). For more detailed information see 'An Approach to the Management of Post-Vaccine Syndrome'.
- **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.
- **Probiotics/prebiotics**
  Patients with post-vaccine syndrome classically have severe dysbiosis with loss of Bifidobacterium. A no-sugar-added, Greek yogurt with both pre- and probiotics is recommended. Suggested probiotics include Megasporebiotic (Microbiome labs), TrueBifidoPro (US Enzymes) and yourgutplus+. Depending on the brand, some pro/prebiotic products can be very high in sugar, which promotes inflammation, so read labels carefully.
- **Spermidine;** 1000-2000 mg (wheat germ extract)/daily
  Spermidine is a naturally occurring polyamine that, like resveratrol, has anti-inflammatory and antioxidant properties. It preserves mitochondrial function and has been shown to reduce cardiovascular disease, and all-cause mortality, prolong lifespan and promote autophagy. Wheatgerm, mushrooms, grapefruit, apples, and mango are high natural sources of spermidine. Wheatgerm supplements contain high amounts of spermidine with good bioavailability. For more detailed information and important contraindications see 'An Approach to the Management of Post-Vaccine Syndrome'.
- **Sunlight and Photobiomodulation** (PBM)
  PBM is also referred to as low-level light therapy, red light therapy, and near-infrared light therapy. Of all the wavelengths of sunlight, near-infrared radiation (NIR-A) has the deepest penetration into tissues. NIR-A in the range of 1000 to 1500 nm is optimal for heating tissues. For more detailed information see 'An Approach to the Management of Post-Vaccine Syndrome'.

ADJUNCTIVE/SECOND LINE THERAPIES

Listed in order of importance.

- **Methylene blue**
  Methylene blue (MB) has a number of biological properties that may be potentially beneficial in vaccine-injured patients. MB induces mitophagy (mitochondrial autophagy) and has anti-inflammatory, antioxidant, neuroprotective, and antiviral properties. MB and photobiomodulation (PBM) have similar beneficial effects on mitochondrial function, oxidative damage, and inflammation, and the two treatments are often combined.

  Low-dose MB is a therapeutic option in patients with brain fog and other neurological symptoms. Patients or their healthcare providers need to purchase high-quality methylene blue powder and formulate an orally administered 1% solution (10 mg MB in 1 ml of water). To achieve this, mix 1 gram of methylene blue powder with 100 ml of water.

  Use a dropper bottle to administer — 1 drop of 1% solution is approximately 0.5 mg of methylene blue).

  Dosing of LDMB:

  - Start with 5 mg (.5 ml or 10 drops) twice daily for the first week.
  - Then gradually increase the dosage every 2-3 days (guided by symptoms - i.e., improvement in fatigue and/or cognitive improvement) until you reach a maximum of 30 mg (3 ml) per day.
  - Take the 7th day off every week to allow the body to "reset".

  The optimal dose is highly individualized and each patient needs to find the right dose for them.

  LDMB will cause your urine to be blue or blue-green, and may stain teeth. Some patients may experience a Herx reaction. A Herx reaction may cause fatigue, nausea, headache, or muscle pain. If you experience a Herx reaction, stop the protocol for 48 hours and then resume again slowly.

  DO NOT take MB if you are pregnant or breastfeeding.

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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

To read more about the safety of the vitamins and nutraceuticals listed on the FLCCC protocols during pregnancy, please visit-geni.us/PregnancySupplements

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.

- **Nigella sativa;** 200-500 mg encapsulated oil twice daily. (continued from page 2)
  The seeds and oil of Nigella sativa have been used as a medical agent for thousands of years. The most important active component is thymohydroquinone. Nigella sativa has antibacterial, antifungal, antiviral (SARS-CoV-2), anti-inflammatory, antioxidant, and immunomodulatory properties. For more detailed information and important contraindications see 'An Approach to the Management of Post-Vaccine Syndrome'.

- **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.

- **Fluvoxamine;** 50 mg twice daily.
  NOTE: 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.

- **Magnesium;** A starting dose of 100 to 200 mg daily is suggested, increasing as tolerated up to 300 mg to 400 mg daily.
  There are at least 11 different types of magnesium that can be taken in supplement form with varying bioavailability. Generally, organic salts of Mg have a higher solubility than inorganic salts and have greater bioavailability. See 'An Approach to the Management of Post-Vaccine Syndrome' for further information and important dosing precautions.

- **Omega-3 fatty acids;** we suggest a combination of EPA/DHA with an initial dose of 1 g/day (combined EPA and DHA) and increasing up to 4 g/day (of the active omega-3 fatty acids).
  Omega-3 fatty acids have anti-inflammatory and cardioprotective effects and play an important role in the resolution of inflammation by inducing resolvin production. Furthermore, Omega-3 fatty acids are believed to afford potent vasculoprotective effects, by improving endothelial function, limiting vascular inflammation, reducing thrombosis, and limiting reactive oxygen species production. Fish, particularly wild Atlantic (or Alaskan) salmon, are a good source of Omega-3 fatty acids. Omega-3 supplements include Vascepa™ (icosapent ethyl; an ethyl ester of eicosapentaenoic acid [EPA]), Lovaza ™ (a combination of ethyl esters of EPA and docosahexaenoic acid [DHA]) as well as "regular fish oil supplements" containing a combination of EPA/DHA. It is now widely appreciated that "EPA and DHA are metabolized to different mediators and are equally important with respect to cardiovascular protection (and inflammation)."

- **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.
  NAC, the precursor of reduced glutathione, penetrates cells where it is deacetylated to yield L-cysteine, thereby promoting GSH synthesis. Oral administration of NAC likely plays an adjuvant role in the treatment of the vaccine injured. Oral Glutathione is poorly absorbed and is therefore not recommended. A combination supplement that contains acetyl glutathione, NAC and Vitamin C may enhance the bioavailability of glutathione.

- **Cardio Miracle™ and L-arginine/L-citrulline supplements;**
  Cardio Miracle is a supplement with over 50 ingredients formulated to increase nitric oxide (NO) production. The supplement contains L-arginine, L-citrulline, Beetroot (high in dietary nitrates), L-Ornithine, CoQ10, as well as a blend of fruit and vegetable phytonutrients.

- **Sildenafil with or without L-arginine-L-Citrulline;** doses titrated up from 25 to 100 mg 2-3 times daily with L-arginine/L-citrulline powder twice daily
  May be helpful for brain fog as well as microvascular disease with clotting and poor perfusion. It is noteworthy that curcumin, resveratrol, EGGG, and valproic acid all potentiate phosphodiesterase 5 (PDE5) inhibitors.

- **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.

- **Hydroxychloroquine (HCQ);** 200 mg twice daily for 1-2 weeks, then reduce as tolerated to 200 mg/day.
  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. Thus, in patients with positive autoantibodies or where autoimmunity is suspected to be a prominent underlying mechanism, HCQ should be considered earlier. Note: HCQ will limit the effectiveness of intermittent fasting.

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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.

Baseline Testing

We recommend a number of simple, basic screening tests that should be repeated, as clinically indicated, every 4 to 6 months:

- CBC with differential and platelet count
- Standard blood chemistries, including liver function tests
- D-Dimer—as a marker of clotting activation
  Myocarditis

(continued from page 3)

- **Low dose corticosteroid;** 10–15 mg/day prednisone for 3 weeks. Taper to 10 mg/day and then 5 mg/day, as tolerated.
- **"Mitochondrial energy optimizer"** with pyrroloquinoline quinone (e.g., Life Extension Energy Optimizer or ATP 360®).
- **Behavioral modification, relaxation therapy, mindfulness therapy, and psychological support.**
  May help improve patients' overall well-being and mental health. Suicide is a real problem in vaccine-injured patients. Support groups and consultation with mental health professionals are important. Tai Chi, a health-promoting form of traditional Chinese martial art, has been shown to be beneficial for preventing and treating diseases including long COVID. Yoga has immunomodulating properties that may be beneficial in vaccine-injured patients.

THIRD LINE THERAPIES

- **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. Please refer to 'An Approach to the Management of Post-Vaccine Syndrome' for treatment information, references, and other important details.
- **Low Magnitude Mechanical Stimulation (LMMS or Whole-Body Vibration)**
  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. This therapy is offered by Physical Medicine and Rehabilitation Centers, or a device may be purchased for home use (https://www.juvent.com/health) similarly with noninvasive brain stimulation (NIBS).
- **Patients with elevated homocysteine levels**
  Such patients may benefit from treatment with 800 ug of 5-methyl tetrahydrofolate (5-MTHF), the most biologically active form of folic acid. Supplementation with folic acid alone will paradoxically increase homocysteine levels, particularly in patients with MTHFR polymorphism. In addition, B complex vitamins containing B2 (riboflavin) and Vitamin B6, magnesium, and Vitamin D should be added.

OTHER POTENTIAL TREATMENTS

- **Plasmapheresis**
  Improves systemic cytokine levels, coagulopathy, and immune responsiveness in patients with severe COVID with a potential mortality benefit. However, it 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.
- **Valproic acid;** Depakote, 250mg 2-3 times daily.
  Valproic acid has anti-inflammatory effects and polarizes macrophages towards an M2 phenotype. Histone deacetylase (HDAC) inhibitors are being studied for neural regeneration. In addition, valproic acid has important anticoagulant and anti-platelet effects and is an inducer of heat shock proteins. Valproic acid may be helpful for neurological symptoms. Treatment should be limited to less than 6-9 months due to the concern for the loss of brain volume particularly in those patients with cognitive dysfunction. In a cerebral ischemia/hypoxia model, resveratrol markedly enhanced the neuroprotective effects of valproic acid. Furthermore, resveratrol has been reported to reverse the toxicity of valproic acid. These data suggest that resveratrol (in a dose of 500 mg–1000 mg twice daily) should be recommended in patients prescribed valproic acid.
- **Induced hyperthermia and Cold Hydrotherapy**
  The role of sauna bathing and cold therapy (cold showers, cold baths) in patients with long COVID and vaccine injury is unknown. Regular sauna bathing has been proven to reduce all-cause and cardiovascular mortality, prolong life span, improve exercise performance, and improve the outcome of patients with neuropsychiatric disease. Induced hyperthermia increases the expression of heat shock proteins, which activates autophagy. In addition, heat therapy increases the expression of cell stress pathways, has antioxidant and anti-inflammatory effects, and improves mitochondrial function. Refer to 'An Approach to the Management of Post-Vaccine Syndrome' for more information.
- **Pentoxifylline (PTX);** PTX ER, 400 mg three times daily.
  Should be considered in those patients with severe microcirculatory disturbances. PTX is a non-selective phosphodiesterase drug that has anti-inflammatory and antioxidant effects. In addition, PTX improves red blood cell deformability and reduces blood viscosity, so can mitigate the hyper-viscosity and RBCs hyper-aggregation, which is linked with the development of coagulopathy in the vaccine-injured.
- **Maraviroc;** 300 mg orally twice daily.
  If 6 to 8 weeks have elapsed and significant symptoms persist despite the above therapies, this drug can be considered. Note Maraviroc can be expensive and has a risk of significant side effects and drug interactions. Maraviroc is a C-C chemokine receptor type 5 (CCR5) antagonist. While many long COVID and post-vaccine patients have been treated with Maraviroc, the role of this drug requires further evaluation.

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- CRP—as a marker of ongoing inflammation
- Early morning cortisol—some patients develop autoimmune adrenal failure
- TSH—to exclude thyroid disease
- Homocysteine level (normal 5-15 µmol/l)
- HbA1C—Vaccine-injured patients are at an increased risk of developing diabetes
- Troponin and pro-BNP to exclude cardiac disease.
- CMV, EBV (early antigen-D IgG or nuclear antigen IgG), Herpes simplex, HHV6 and mycoplasma serology/PCR—to exclude viral/bacterial reactivation (Lyme (Bb), Bartonella and Babesia tick-borne diseases)
- Vitamin D level (25OH Vitamin D)

Disease-specific strategies

Please note that 'An Approach to Management of Post-Vaccine Syndrome' includes a list of disease-specific therapeutic adjuncts, and a fuller list can be found there. The most frequently treated disorders are:

- Nerve disorders (POTS, neuropathies), Bell's Palsy
- Brain fog, fatigue, visual disturbances
- Depression
- Clotting and bleeding disorders
- Myocarditis
- Autoimmune diseases
- Tinnitus
- Loss of taste and smell
- MCAS/histamine issues
- Hair loss

OTHER POTENTIAL TREATMENTS

(continued from page 4)

- **Sulforaphane (broccoli sprout powder);** 500 mcg-1g twice daily.
  While sulforaphane has many potential benefits in patients with COVID, long COVID, and post-vaccine syndrome, there is limited clinical data to support this intervention. See 'An Approach to the Management of Post-Vaccine Syndrome' for details.

- **Dandelion (Taraxacum officinale);** 4-10 g three times daily (20-30 mg/ml in hot water).
  The root, flower, and leaves of dandelion contain an array of phytochemicals that have anti-inflammatory, antioxidant, hypolipidemic, antimicrobial, and anticoagulant properties. It is widely reported that dandelion is effective for 'detoxifying' spike protein. See 'An Approach to the Management of Post-Vaccine Syndrome' for contraindications, references, and other details.

- **VEDICINALS® 9**
  This unique phytopharmaceutical-based therapeutic suspension consists of nine bioactive compounds with antiviral, anti-inflammatory, immune-modulatory, antipyretic, and analgesic properties. The compounds include Baicalin, Quercetin, Luteolin, Rutin, Hesperidin, Curcumin, Epigallocatechin Gallate, Piperine, and Glycyrrhizin. A number of these compounds are included in our protocol and the additional benefit of this 9 phytopharmaceutical combination over more widely available flavonoid combinations is unknown.

- **C60 or C60 fullerenes**
  C60, short for Carbon 60, is composed of 60 carbon atoms forming something that looks like a hollow soccer ball. Considered a "free radical sponge" and the single most powerful antioxidant ever discovered, its discoverers were awarded the Nobel Prize for Chemistry in 1996.

- **Intravenous immunoglobulin (IVIG) treatment**
  The role of IVIG in the treatment of vaccine injury is unclear. The response to IVIG in the general population of vaccine-injured patients is mixed, with very few showing long-term improvements. Many patients who report an initial improvement will relapse in 2 to 3 weeks. Other patients report no benefit, while some appear worsened. Due to the presence of non-neutralizing anti-SARS-CoV-2 antibodies and anti-ACE-2 antibodies, etc., the real possibility exists that IVIG will cause antibody-dependent immune enhancement (ADE) with a severe exacerbation of symptoms. IVIG is, however, recommended in specific autoimmune syndromes, which include Guillain Barré Syndrome, transverse myelitis, and immune thrombocytopenia. These patients should concomitantly be treated with the core immune-modulating therapies.

- **Immunosuppressive therapies**
  As a rule, immunosuppressive therapy should be avoided, as these drugs may exacerbate the immune dysfunction in vaccine-injured patients and prevent the restoration of immune homeostasis. A trial of immunosuppressive therapy may be indicated in patients with an established autoimmune syndrome who have failed other therapeutic interventions.

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