TBI Therapy
Regenerative Therapy for Brain Injury

Treatment Protocols and Procedures

In summary, the study procedures for each patient visit are as follows. (Note: This is just an outline of a possible encounter and treatment scenario).

Phase 0: Pre-consult/ Intake completion and Diagnostics

TBI Intake Questionnaire is completed and submitted by patient

Consent forms signed, WAVi EEG scan, Neurocognitive Testing with PHQs, physician consultation and exam, including clearance for all treatments, TBI Symptom evaluation, Standardized Assessment of Concussion, AMP-TBI Score Assessment, Laboratory assessment, Wellness reporting (All diagnostics may be used for optional AMP-TBI Scoring).

Phase 1: Intranasal Insulin and Oxygen Therapy

Intranasal Insulin:

20 units of Humulin R (diluted into 1 cc solution with 8 cc sterile normal saline plus 1cc Magnesium chloride-optional) shall be delivered with a 1 cc syringe at the olfactory mucosa in each naris with the patient supine and neck extended for 10 minutes. See intranasal insulin instructions at https://tbitherapy.com/training/. Note: Insulin dilution may be done in 10 cc or 20cc vials. These vials do not have to be refrigerated if used within three months but should be stored either in a refrigerator or dark place at room temperature.

Also note: It is recommended to administer the intranasal insulin treatments on the same day just before the normo-baric or hyperbaric oxygen treatment. It is also recommended to provide the patients with an electrolyte supplement such Liquid IV (Liquid I.V. - Faster Hydration Than Water Alone (liquid-iv.com) or Extreme Hydration Formula (Extreme Hydration Formula - Stay Extremely Hydrated) right after receiving the intranasal insulin.

Normobaric Oxygen Therapy:

60 min at 5-8 L/min x 10 days (two 5-minute air-breaks are recommended after 15 min and after 35 min)

(alternative)

Hyperbaric Oxygen Therapy

1 treatment at 1.5 to 1.75 ATA x 60 minutes for 10 days

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Phase 2: Intranasal PRP (Super Oxygenated Plasma Cocktail) Prep and Administration

Phase 2, ideally, should begin early as 1-2 days after finishing Phase 1. Depending on patient progress and tolerance to the intranasal insulin and oxygen therapies, practitioners may also choose to a few days longer period before beginning Phase 1.

Blood draw:

50 cc of blood shall be taken from a peripheral vein from each subject

IV administration (Optional)

Patient shall then be infused intravenously over 60 minutes with an enhanced Myer's nutrient cocktail in 500cc NS with the following nutrients added: 10 cc Ascorbate (500mg/cc), 5 cc Glutathione (200mg/cc), 3 cc Magnesium chloride (200mg/cc), 2 cc KCl (2MeQ/cc), 1 cc Methylcobalamin (5000mcg/cc), 1 cc Calcium chloride (100mg/cc), 1 cc Pyridoxine (100mg/cc), 1 cc Dexpanthenol (250mg/cc), 1 cc B-complex (100mg/cc), 2 cc NAD+ (100mg/cc).

Super-Oxygenated Autologous Plasma (SOAP) preparation

Patients shall have 50 cc of their peripheral venous blood drawn using a 60-cc syringe containing 10 cc ozone (O_3) at a concentration of 20 microgram/cc (if possible).

The patient's blood and ozone mixture is then injected, divided equally, into 3 sterile yellow-topped tubes (8.5 cc tubes containing sodium citrate as an anticoagulant) and then centrifuged at 3400 rpm for 8-10 min.

While being centrifuged, the practitioner or technician should make up the following solutions:

-In a **3-cc syringe,** the practitioner should draw up (with an 18 gauge draw needle): **1 cc D50, ½ cc Ascorbate (500mg/cc), ½ cc Magnesium chloride (200mg/cc).**

-In a separate **3-cc syringe,** the practitioner should draw up (with an 18 gauge draw needle): ½ cc NAD+ (100mg/cc), ½ cc B12 (as Methylcobalamin at 5000mcg/cc), and ½ cc glutathione (at 200mg/cc).

-In a **5-cc syringe,** the practitioner should draw up (with an 18 gauge draw needle): 4 cc Ropivacaine (0.5%), ½ cc Neo-synephrine (10mg/cc) and attach a nasal atomizer to the luer lock tip of the syringe.

-In a **20-cc syringe,** the practitioner should draw up (with an 18 gauge draw needle): 10 cc of

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ozone at 20ug/cc (20 gamma)

After the Ropivacaine / Neo-synephrine has been filled in the 5 cc syringe, the practitioner should administer it with the nasal atomizer (2.5 cc to each naris) with the patient sitting upright (with head slightly tilted back). The patient shall then hold nose and gently massage the solution into their tissues for approximately 2-3 minutes before blowing their nose. The patient may swallow a small amount of this solution so practitioner should be ready with some water to offer to him or her after the solution has been atomized.

Once the centrifugation of the blood is completed, the practitioner shall carefully extract 7cc of autologous plasma from 2 yellow top tubes (with an 18g 3.5 in needle). It is recommended that the practitioner do this extraction of plasma while wearing a mask or with the plasma collection tubes under a laminar flow hood (or comparable hood).

Using the female-to-female luer lock adapter, transfer 7 cc of plasma to the 20-cc syringe containing 10 cc ozone. The ozone is then mixed with the plasma which is then transferred back to the 10 cc syringe.

Then each of the contents of the 3 cc syringes are attached to the luer lock adapter beginning with the D50, ascorbate, magnesium cocktail and then the NAD+, B12, glutathione cocktail. The total volume of the 10 cc syringe will then equal 10.5 cc of the SOAP cocktail (Super-Oxygenated Autologous Plasma).

The SOAP cocktail may now be administered via a specialized catheter (5.25 cc into the superior 3rd of each naris) with the subject supine and neck fully extended into a headrest of a medical table that is perpendicular to the floor. Subject must remain in this extended position for at 8-10 minutes after administration of the SOAP cocktail. If a subject sneezes, swallows, or is not in the correct position for the intranasal Soap cocktail delivery, the procedure must be repeated. This is the reason to have the extra plasma available in the 3rd plasma collection tube.

Prognostic Assessments (To Be Done before Phase 3—approximately 2-4 weeks after baseline diagnostics): WAVi EEG scan, Neurocognitive Testing with PHQs, Physician follow up and exam, TBI Symptom evaluation, Standardized Assessment of Concussion, AMP-TBI Score Assessment, Laboratory assessment-optional, Wellness reporting (All diagnostics may be used for optional AMP-TBI Scoring).

Phase 3: Intranasal Insulin and Oxygen Therapy

Phase 3 is a repeat of Phase 1: Intranasal Insulin and Oxygen Therapy (as necessary for **mild-moderate TBI patients**)

Phase 3 may be started as early as 2 days after finishing Phase 2. Depending on patient progress

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and tolerance to the intranasal PRP (SOAP cocktail), practitioners may also choose to wait a longer period before beginning Phase 2. (Note: Many patients will require a break of approximately 2 weeks between therapies making the beginning of Phase 3 approximately 14-30 days after initial consultation and baseline diagnostics of Phase 0).

Phase 4: Intranasal PRP (Super Oxygenated Plasma Cocktail) Prep and Administration

Phase 4 is a repeat of Phase 2:

Phase 4, ideally, should begin early as 1-2 days after finishing Phase 3. Depending on patient progress and tolerance to the intranasal insulin and oxygen therapies, practitioners may also choose to wait a few days longer period before beginning Phase 4.

Prognostic Assessments (To Be Done before Phase 5—approximately 4-6 weeks after baseline diagnostics): WAVi EEG scan, Neurocognitive Testing with PHQs, Physician follow up and exam, TBI Symptom evaluation, Standardized Assessment of Concussion, AMP-TBI Score Assessment, Laboratory assessment-optional, Wellness reporting (All diagnostics may be used for optional AMP-TBI Scoring).

Phase 5: Intranasal Insulin and Oxygen Therapy

Phase 5 is a repeat of Phase 1: Intranasal Insulin and Oxygen Therapy (as necessary **for moderate-severe TBI patients)**

Phase 5 may be started as early as 2 days after finishing Phase 4. Depending on patient progress and tolerance to the intranasal PRP (SOAP cocktail), practitioners may also choose to wait a longer period before beginning Phase 4.

Phase 6: Intranasal PRP (Super Oxygenated Plasma Cocktail) Prep and Administration

Phase 6 is a repeat of Phase 2:

Phase 6, ideally, should begin early as 1-2 days after finishing Phase 5. Depending on patient progress and tolerance to the intranasal insulin and oxygen therapies, practitioners may also choose to wait a few days longer period before beginning Phase 6.

Prognostic Assessments (To Be Done before Phase 7—approximately 6-8 weeks after baseline diagnostics): WAVi EEG scan, Neurocognitive Testing with PHQs, Physician follow up and exam, TBI Symptom evaluation, Standardized Assessment of Concussion, AMP-TBI Score Assessment, Laboratory assessment-optional, Wellness reporting (All diagnostics may be used for optional AMP-TBI Scoring).

Phase 7: Intranasal Insulin and Oxygen Therapy

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Phase 7 is a repeat of Phase 1: Intranasal Insulin and Oxygen Therapy (as necessary **for severe TBI patients)**

Phase 7 may be started as early as 2 days after finishing Phase 6. Depending on patient progress and tolerance to the intranasal PRP (SOAP cocktail), practitioners may also choose to wait a longer period before beginning Phase 4. (Note: Many patients will require a break of approximately 2 weeks between therapies).

Phase 8: Intranasal PRP (Super Oxygenated Plasma Cocktail) Prep and Administration

Phase 8 is a repeat of Phase 2:

Phase 8, ideally, should begin early as 1-2 days after finishing Phase 7. Depending on patient progress and tolerance to the intranasal insulin and oxygen therapies, practitioners may also choose to wait a few days longer period before beginning Phase 8.

Prognostic Assessments (To Be Done 2-4 weeks after Phase 8—approximately 12 weeks after baseline diagnostics): WAVi EEG scan, Neurocognitive Testing with PHQs, Physician follow up and exam, TBI Symptom evaluation, Standardized Assessment of Concussion, AMP-TBI Score Assessment, Laboratory assessment-optional, Wellness reporting (All diagnostics may be used for optional AMP-TBI Scoring).

Procedural Safety and Precautions

The only medications utilized in this treatment algorithm are oxygen (in the form of hyperbaric oxygen therapy) and insulin as Humulin R U 100.

Safety profiles of the hyperbaric oxygen at 1.5 ATA are well established and present a very low risk in clinics who follow the NFPA 99 guidelines of the United Hyperbaric Medical Society's guidelines (UHMS).

Hyperbaric oxygen: There is a slight risk of oxygen toxicity at higher oxygen pressures, but primarily at levels of 2.8 to 3.0 ATA.

The CNS effects secondary to oxygen toxicity is known as the Bert effect. This can occur with hyperbaric oxygen therapy in a dose-dependent correlation. The overall risk may be as frequent as 1 in 2000 to 3000 treatments. However, this risk may be as high as 1 in 200 at higher pressures (2.8 to 3.0 times normal atmospheric pressure or one atmosphere absolute (ATA)) and as low as 1 in 10,000 for treatment at 2 ATA (atmosphere absolute air) or less. The incidence of displaying CNS symptoms secondary to oxygen toxicity is 2%."

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https://www.ncbi.nlm.nih.gov/books/NBK430743/#article-26493.r2

Intranasal Insulin and PRP Safety

Bloody noses and swallowing plasma or local anesthesia have been the biggest side-effects of IN PRP. If the patient swallows the insulin, he or she may need some form of sweet substance to eat to prevent a drop in blood sugar. Sneezing is another danger of the treatment. Using good sterile technique will prevent infection.

"The only unpleasant side effect of intranasal Humulin R is the distaste of it and ingestion by swallowing. As we know, the stomach acids rapidly denature the proteins that make up insulin such that any effects of the drug are eliminated such that blood sugar will not be affected. (This is why insulin is regularly injected by diabetics because no oral insulin can work)."

https://tbitherapy.com/insulin/

See the https://tbitherapy.com/training/ for more information about safety of each of these procedures as well as adjunctive TBI treatment procedures.

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