



CONSENT FOR TREATMENT

IV Iron Infusion Procedure

PURPOSE AND BACKGROUND

As a patient of Nourished MedSpa and Wellness Center, I have requested intravenous iron infusion therapy. I am aware that iron infusions have been found to be necessary for the following reasons:

- A. For patients needing iron supplementation who are unable to tolerate compounds given orally; *or*
- B. For patients who are losing iron (blood) at a rate too rapid for oral intake to compensate for the loss; *or*
- C. For patients with a disorder of the gastrointestinal tract, such as inflammatory bowel disease (ulcerative colitis and Crohn's disease), in which symptoms may be aggravated by oral iron therapy; *or*
- D. For patients who are unable to maintain iron balance on treatment with hemodialysis; *or*
- E. For patients with iron deficiency anemia associated with peritoneal dialysis and non-dialysis-dependent (NDD) chronic kidney disease; *or*
- F. For patients who are donating large amounts of blood for autologous programs; *or*
- G. For patients who repeatedly fail to heed instructions for oral iron supplementation or are incapable of accepting or following them; *or*
- H. For patients with iron deficiency and chemotherapy-induced anemia; *or*
- I. For patients with heart failure and iron deficiency, with or without anemia; *or*
- J. For patients with iron deficiency anemia due to heavy uterine bleeding; *or*
- K. For patients with iron deficiency following gastric bypass surgery and/or subtotal gastric resection and who exhibited decreased absorption of oral iron.

I hereby certify that I am not forgoing any proven treatments of any illness or ailment in favor of this treatment.

Intravenous iron products provide supplemental iron, thereby increasing iron and ferritin levels while decreasing the total iron binding capacity. Intravenous iron products are used for the treatment of iron deficiency with or without anemia. IV iron therapy is as effective but somewhat more dangerous and considerably more expensive than oral therapy. The most common use for intravenous iron is in hemodialysis patients. According to guidelines from the National Kidney Foundation (NKF), a trial of oral iron is acceptable in the hemodialysis patient, but is unlikely to maintain adequate iron balance. The NKF guidelines state that, to achieve and maintain a hemoglobin level of 11 to 12 g/dL (hematocrit of 33 % to 36 %), most hemodialysis patients will require intravenous iron on a regular basis.

PROCEDURE

An intravenous (IV) injection involves various vitamins and medicines to be given into a vein. The main sites to access veins are in the bends of the elbows. The hands and forearms may also be used. The ideal site depends on quality of vein access, age, size, and amount of medicine in the injection. Venofer, (iron sucrose, USP) can be given in doses of 100 mg undiluted as a slow intravenous injection over 2 to 5 mins, or as an infusion of 100 mg diluted in 100 ml of 0.9 % NaCl or as a 200 mg undiluted as a slow intravenous injection over 2 to 5 mins on 5 different occasions for CKD patients. There is limited experience with administration of 500 mg of Venofer diluted in a maximum of 250 ml of 0.9 % NaCl over a period of 3.4 to 4 hours on day 1 and 14. In peritoneal dialysis, administer Venofer in 3 divided doses, given by slow intravenous infusion over a 28-day period: 2 infusions each of 300 mg over 1.5 hours; 14 days apart followed by one 400 mg infusion over 2.5 hours 14 days later. Dilute Venofer in a maximum of 250 ml of 0.9 % NaCl.

RISKS AND COMPLICATIONS

- Some redness and swelling at the injection site may occur. This should start to get better within forty-eight (48) hours.
- Discomfort, bruising and pain at the site of injection.
- Inflammation of the vein used for injection, phlebitis, metabolic disturbances, and injury.
- In rare cases, IV therapy can cause diarrhea, peripheral vascular thrombosis, localized vein irritation or infection, sepsis, itching, transitory exanthema, urticaria, feelings of swelling of the whole body.
- In extremely rare cases, severe allergic reaction, anaphylaxis, infection, cardiac arrest and death.
- I may even feel a bit "off" for a few days after treatment.
- Sensitivity to any of the ingredients is a contraindication.

I do not expect the physician(s) to anticipate and or explain all risk and possible complications. I rely on the physician(s) to exercise judgment during the course of treatment with regards to my procedure. Intravenous Iron Products may cause clinically

significant hypotension. Excessive therapy with Intravenous Iron Products can lead to excess storage of iron with the possibility of iatrogenic hemosiderosis. Patients receiving Intravenous Iron Products require periodic monitoring of hematologic and iron parameters (hemoglobin, hematocrit, serum ferritin and transferrin saturation).

PROPOSED BENEFITS

The following benefits are anecdotal and are in no way proven with scientific studies:

- More energy, mental alertness and stamina for everyday tasks
- Healthier immune systems
- Improves sleep
- Increases metabolism, thereby aiding in weight loss
- Reduces allergies, stress and depression
- Improves mood stabilization
- Lessens frequency and severity of migraines and headaches

ALTERNATIVES

This is strictly a voluntary procedure. No treatment is necessary or required. Other alternative treatments which vary in sensitivity, effect and duration include: diet and exercise or oral vitamin therapy.

RESULTS

I am advised that though good results are expected, the possibility and nature of complications cannot be accurately anticipated and there can be no guarantee as expressed or implied either to the success or other result of treatment. I am aware that other unforeseeable complications could occur. I am aware that the duration of treatment is dependent on many factors including but not limited to: age, sex, tissue condition, my general health and lifestyle conditions. Clinical results will vary per patient.

QUESTIONS

This procedure has been explained to me by the staff of Nourished MedSpa and Wellness Center. I have had an opportunity to ask any questions and research the procedure to my satisfaction.

CONSENT

I understand that my consent and authorization for this procedure is strictly voluntary. I have already read and signed the Clinic's general consent and understand that it is still in effect. By signing this informed consent form, I hereby grant authority to Nourished MedSpa and Wellness Center and Dr. Jason Carter, MD (or other delegated medical providers for Nourished MedSpa and Wellness Center) to perform IV iron infusion and/or administer any related treatment as may be deemed necessary or advisable in the diagnosis and treatment of my condition. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.

The nature and purpose of this procedure and the complications and side effects have been fully explained to me. Alternative treatments and their risks and benefits have been explained to me and I understand that I have the right to refuse treatment. I agree to adhere to all safety precautions and instructions after the treatment. I have been instructed in and understand post treatment instructions and have been given a written copy of them. I understand that no refunds will be given for treatments received. No guarantee has been given or implied by anyone as to the results that may be obtained from this treatment.

I have read this informed consent and certify that I understand its contents in full. All of my questions have been answered to my satisfaction and I consent to the terms of this agreement. I have had enough time to consider the information given me by my physician/practitioner and feel that I am sufficiently advised to consent to this procedure. I accept the risks and complications of the procedure. I certify that if I have any changes occur in my medical history I will notify Nourished MedSpa and Wellness Center immediately.

I hereby voluntarily consent to this procedure and release Nourished MedSpa and Wellness Center, medical staff, and all associated professionals from liability associated with the procedure. I certify that I am a competent adult of at least 18 years of age and am not under the influence of alcohol or drugs. This consent form is freely and voluntarily executed and shall be binding upon my spouse, relatives, legal representatives, heirs, administrators, successors and assigns.

Patient Name (please print)

Patient Signature

Date

Performed by (please print name and title)

Practitioner Signature

Date



PRE-TREATMENT INSTRUCTIONS

IV Vitamin Therapy Procedure

1. IV therapy may take up to 90 minutes, depending on the infusion and other factors. Please plan your schedule accordingly, to allow for adequate time for your infusion.
2. Always drink 2 large glasses of water (24 oz.) before and after your treatment.
3. Eat a good meal before arriving for your therapy or bring a meal with you to eat during the treatment. Include carbohydrates and protein in the meal. A combination of carbs and protein will help to keep the blood sugar stable during the treatment.
4. Do not drink soda, coffee or tea prior to your treatment. Caffeine dehydrates you, and makes it more difficult to start your IV.
5. Do not take vitamin and/or mineral supplements prior to your treatment unless otherwise specified by Dr. Carter.
6. Do not exercise 2 hours before or after your treatment.
7. Inform the doctor and technician of any changes in medication.
8. Inform the doctor and I.V. technician of any changes in your health status since your last treatment (chest pain, shortness of breath, weight gain/loss, leg pain, bladder problems, etc.)
9. Inform the doctor and technician if you are pregnant or nursing.

DURING YOUR I.V. TREATMENT

1. Inform your I.V. technician immediately if you feel dizzy, nausea or a vitamin taste in your mouth.
2. Bathroom: Always ask your technician for assistance when using the bathroom. When getting up to use the bathroom, roll the IV pole into the bathroom using your non-IV arm. If your blood backs up into the tubing, do not be alarmed. Sit down, and the fluid in the drip chamber should continue and the blood will return to you. If this does not happen, tell your technician immediately.
3. Do not stand up too quickly during or after treatment, to avoid dizziness.

Please contact our office at 903-357-5108 with any questions or concerns.



POST-TREATMENT INSTRUCTIONS

IV Vitamin Therapy Procedure

1. At the end of your treatment, a bandage will be applied to the IV site. If you bruise easily, leave the dressing on for one hour. Otherwise, it can be removed after 15 minutes. **CALL THE CLINIC IF YOU OBSERVE ANYTHING UNUSUAL.**
2. Drink at least 24 ounces of water.
3. Get plenty of rest.
4. If any problems should occur after your treatment, the following measures should be taken:
5. Inform our office immediately if a reaction has occurred. If immediate care is needed, call Dr. Carter, proceed to the nearest emergency room, or call 911.

Please contact our office at 903-357-5108 with any questions or concerns. If you have an emergency or urgent pressing clinical issue, call Dr. Carter at 903-818-3467. Texting is the best way to reach Dr. Carter.

Please make an appointment for follow-up and reassessment in 4 weeks.

Patient Name (please print)

Patient Signature

Date