

Treating TBI & PTSD through Hyperbaric Oxygen Therapy

The FDA and our DOD-VA have not approved the use of hyperbaric oxygen therapy (HBOT) for traumatic brain injuries or post traumatic stress. This leaves our wounded Heroes to the “band aids” offered by the VA in the way of drugs and many unproven other questionable activities. Drugs by the boat loads are auto shipped to our wounded Veterans through the VA and this has driven them deeper into their dark world and thus closer to suicide. The drugs don’t work and our Heroes move to alcohol or illegal drugs for relief.

The American public needs to be enlightened about the enhancements made through HBOT therapy and we need the FDA and our politicians to accept this because it does work. If we could get our government and the VA onboard we would not have to send our wounded heroes away from their families to get the treatment they deserve paid for by donations.

The Reserve Officers Association (ROA) - Indiana Chapter 7 (Central IN) in connection with The Military / Veterans Coalition of Indiana (TMVCI) is raising funds to conduct a clinical trial pilot at Riverview Hospital in Noblesville, IN to prove to the Indiana General Assembly the viability of hyperbaric oxygen therapy (HBOT) as a primary treatment for veterans suffering from a traumatic brain injury and/ or post traumatic stress. Proving the efficacy of hyperbaric oxygen therapy should provide the impetus for the Indiana General Assembly to pass legislation directing a statewide study.

Advocates of TMVCI and ROA [BG James L. Bauerle USA (Ret.) and LTC Ron Martin USA (Ret.)] have worked closely for three years to get a statewide program. In 2014, fifty four (54) members of the Indiana House of Representatives signed on as coauthors to HB1379 authored by Representative Denny Zent. This bill passed unanimously out of the Public Health Committee but died without a hearing in Ways and Means. In 2015, a similar fate happened. The current chairman of the House Ways and Means Committee is Dr. Tim Brown, MD. Dr. Brown is not convinced that Hyperbaric Oxygen Therapy (HBOT) works and noted it is not currently FDA approved. Positive results from this pilot should convince him and other skeptics in the general assembly that HBOT works for TBI-PTS. Representative Milo Smith (District 59) has a brother who suffers from TBI-PTS and has stated he will work to help get his brother included as one of the pilot test patients. Representative Smith will testify supporting this action assuming the treatment proves a positive result.

We have a few veterans from Indiana who have been treated with HBOT and have testified to its efficacy. Additionally, many others treated have provided testimony supporting this treatment (u-Tube videos and written statements. These can be provided.).

Riverview was selected because of their desire and willingness to do this pilot at cost and because they have the equipment and staff willing to do this pilot. The pilot can start

soon after the funds are raised to cover the costs. Riverview's clinical trial is budgeted at \$250K for the two year study. This pilot is an extension of the "cross-over" studies performed by Israeli researchers and Paul Harch in Louisiana.

Results from these studies were very positive (patients showed 80-95% improvement in cognitive functions and there were no negative effects or failures), peer reviewed, and published in various medical journals. This clinical trial will be the 1st in Indiana and Dr Harch is beginning a study at LSU. Several locations throughout the world are currently treating individuals and reporting significant improvement. Unfortunately, the successes are not part of a formalized clinical trial under strict scientific processes. The International Hyperbaric Medical Foundation is trying to get funding to start additional trials within the United States and is working with a few clinics in developing these trials. The more locations conducting trials the better because the FDA requires over a thousand data points to consider before approving.

The pilot will involve blood work, screening, x-rays, pre-treatment assessment, a prescription of hyperbaric oxygen therapy using 100% oxygen at 1.5 Atmospheric pressure for 1 hour (called a dive), for 40 doses to be administered not more than 1 dive every 5 hours. Additional assessments will be conducted during and after treatments. Follow-on assessments will be done periodically for 2 years after to validate the durability of the therapy. The goal is to treat 100 patients. Volunteer patients will be solicited through TMVCI member organizations, American Legion, the Disabled Veterans Association and working with Veterans Treatment Courts in central Indiana (this has the added benefit of gaining support from state judges, prosecutors, defense attorneys, and other members of the courts). The intent is to get as many veterans from Hamilton County and surrounding counties as possible. The research will lay the scientific and clinical groundwork for accelerated treatments for service members and civilians. The clinical trial plan is to go through an Institutional Review Board. Data from the study will be collected on the "Care Vector Platform" which is a data repository and analysis engine available from the International Hyperbaric Medical Foundation. Riverview will have full access to study results from all other studies and will be able to share their results with other medical organizations. This will enhance and support the evidence-based medical validation of the safety and efficacy of HBOT.

Success will be measured by analyzing positive (improvement in cognitive functionality and physical performance) results between before and after assessments using tools to include AMAM, Rivermead and other instruments and be posted on the "Care Vector Platform". Further, success will be collected from testimony by patients and their families on the results. Given time constraints, DOD, and Congressional preoccupation with other issues, the only way to assure successful outcomes for thousands of the disabled brain injured Hoosier is the immediate, rapid conduct of a state clinical trial to prove to State Elected Officials that HBOT works! This initial trial will provide solid proof in INDIANA that a state wide program works.

Treatment across the broad front would be justified by the state and make a real difference to thousands of lives of Hoosiers who continue to languish and suffer from TBI-PTS.

The final phase of this three phase plan would be to submit and have accepted the evidence required to get FDA approval of HBOT 1.5 for TBI-PTS and other brain insults. Then millions of Americans can be treated and have insurance cover the costs. This will have a profound effect on lives, the insurance industry, and society in general.

If you or anyone you know would be willing and ready to help in funding this study, please contact James L. Bauerle at jimbauerle.sr@gmail.com or call him at [317-844-6432](tel:317-844-6432).

Thank you in advance for your help and participation in this life enhancing project for our wounded Heroes. Not all wounds are visible....

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