STUDY PROTOCOL

Hyperbaric Oxygen Therapy for Traumatic Brain injury

PROTOCOL TITLE:	**Hyperbaric Oxygen Therapy for Traumatic Brain Injury**
PROTOCOL NUMBER:	**JMC-TBI-001**
VERSION NUMBER:	**~~9~~10**
VERSION DATE:	**February 21, 2018**
SPONSORED BY:	**Jupiter Medical Center 1210 S. Old Dixie Hwy Jupiter, FL 33458**
PRINCIPAL INVESTIGATOR:	**Barry Miskin, M.D. 1002 S. Old Dixie Hwy, Suite 304 Jupiter, FL 33458**
SUB INVESTIGATOR:	**Lee Fox, MD 1210 S. Old Dixie Hwy Jupiter, FL 33458**
SITE ADDRESS:	**Jupiter Medical Center 1210 S. Old Dixie Hwy Jupiter, FL 33458**

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INVESTIGATOR STATEMENT OF COMPLIANCE AND SIGNATURE:

I confirm that I have read this study protocol Study Number JMC-TBI-001, Version 10 – dated February 21, 2018 ---- including appendices and agree to the performance of the study according to this protocol. I will perform the study in accordance with the procedures described in the protocol and potential later amendments, and will try to contribute to the study in such a way that the targeted time schedule will be fulfilled.

By my professional education and experience, I am licensed to practice medicine and qualified to execute this clinical study in patients.

I will provide training and all necessary information including copies of the study protocol to the staff involved in the performance of the study. I will keep them informed about the general status of the study, including the development and report of any new information learned about the investigated treatment which may influence willingness of participants to participate/continue to participate in the study, and will verify that all tasks are fulfilled thoroughly and in a timely manner.

I will perform the study according to the ICH-GCP Guidelines, the Declaration of Helsinki, national laws and regulations, and according to accepted moral, ethical and scientific standards within clinical research.

I confirm that my facilities (equipment, etc.) are adequate to conduct the study according to the requirements of the study protocol.

A patient will not be enrolled in the study without first providing his/her written informed consent. Only the versions of the Informed Consent that have been reviewed and approved by the local Institutional Review Board (IRB) will be used.

I, or one of the sub-Investigators delegated by me, will review each case report form and confirm the correctness of entries by signature.

I agree to regular monitor visits and to audits/inspections by contracted monitor company and/or by local and national authorities. I will provide original data (e.g., medical records, Imaging) to the monitors and/or auditors/inspectors to allow Source Data Verification. I, sub-Investigators, study coordinators delegated by me, will cooperate in data clarification procedures.

All patients' data will be treated as confidential; patient data will only be transferred in pseudonymous ways. All research data will be property of Jupiter Medical Center.

Investigator Name and Address: _____

_____

_____

Position: _____

Signature: _____ Date: _____

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1. Introduction:

Traumatic Brain Injury (TBI) is a painful, disabling disease of the brain. Several studies have reported improvement in behavioral and cognitive symptoms of TBI using pharmacological therapies such as the use of stimulant medications as well as amantadine. In addition, cognitive rehabilitation techniques are commonly used in most TBI clinical centers with some degree of effectiveness (Arciniegas, Anderson, Topkoff, & McAllister, 2005). Recently, animal and human studies (Harch et al 2012, Harch et al 2007, and Golden et al 2002) have shown promising results in the treatment of TBI with hyperbaric oxygen (HBO). Ischemia has been implicated as a major factor in symptoms of TBI. The lack of oxygenation of the brain cells causes a shift from aerobic metabolism to anaerobic metabolism. This results in acidosis and depletion of cellular energy. The damage from the event propagates to manifest in a myriad of symptoms attributed to TBI (Centers 2011). Penumbra (an area of moderately ischemic brain tissue surrounding an area of more severe ischemia) results from traumatic brain injury. This is an area of brain that has cells that are dormant. They are not getting enough oxygen. Hyperbaric Oxygen Therapy is able to transport oxygen to this area and stimulate the cells to function again, resulting in improvement of traumatically damaged brain tissue.

The use of HBO to treat disease is not new; at 2.0 to 3.0 atmospheres absolute (ATA), it is approved by Medicare for15 diagnoses (Centers 2006). A lower-pressure protocol of HBOT (1.5 ATA) has been under investigation beginning around 1989 (Golden et al, 2002; Harch and Neubauer, 1999, 2004a; Harch et al, 1994, 1996a; Neubauer et al, 1994) The use of HBO for treatment of various wounds and diabetic foot ulcers is thought to be the same process as treating TBI. HBO treatment of diabetic foot ulcers and wounds stimulates healing by oxygenating an area that was not accessible to oxygen prior and prevented healing. This is the same mechanism that HBO uses to heal the brain in TBI. Recent studies using low pressure HBO for TBI at Louisiana State University as well as University of California, Irvine, University of North Dakota, and Georgetown University Medical Center have shown encouraging results (Harch et al 2012).

Oxygen toxicity, with the most severe manifestation being seizure, is possible in all HBOT studies. Lin et al, in 2008, reported a 9% seizure rate at 2.0 ATA. At doses less than 2.0 ATA, toxicity has been noted only with prolonged treatment (Harch 2002).

2. Research Objectives and Hypothesis

This study is designed to test the hypothesis that patients with TBI treated with HBO will show improvement in function and an increased blood flow as evidenced by single-photon emission computerized tomography (SPECT) scan. Improvement is evidenced by increase in number of pixels on SPECT Scan and increased brain metabolism. Improvement may also be identified via cognitive assessments administered by Jupiter Medical Center Research Department.

3. Study Population:

100 male or female patients over the age of 18 years old that have experienced a TBI at least one year old from Visit 1A.

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4. Study Design and Research Methods

Patients with TBI who have may have abnormal findings including hemorrhagic cortical contusions or petechial or foci of altered signal that represents white matter injury are candidates for inclusion in this trial. MRI, CT or SPECT scans showing changes consistent with TBI and or medical history of TBI as evidenced by medical records will be screened for treatment with HBO. Each recruited patient will undergo 5 times-a-week HBO treatments to 1.5 ATA (atmospheres absolute).

Prior to study enrollment patients will be screened for eligibility by evaluating CT scan of head without contrast, MRI of brain or SPECT Scan, neurological evaluation from neurologist and history and physical from patient's primary medical physician. The neurological evaluation will determine whether patients have contraindications for HBO treatment and meet study criteria.

After obtaining informed consent of patient, each patient will have a baseline SPECT scan, cognitive assessment, and physician evaluation prior to first treatment. The treatment regimen will be completed in 40 treatment increments. After 40, 80, and 120 treatments SPECT scan, cognitive testing and physician visit will be performed to document progress of the treatment. Cognitive assessment will include the Trail Making Test Parts A and B (See Appendix 1) performed by the research coordinator. Patients will be seen by Principal Investigator to assess level of disability at each interval; the United States Department of Veterans Affairs' Evaluation of Cognitive Impairment and Subjective Symptoms (VAECI) (2012) tool (See Appendix 2) will be utilized during the physician's evaluation as an objective measure of the patient's level of disability. At the completion of study regimen, patient will again be seen by neurologist to assess level of function and cognitive status. HBO treatments may be adjusted for patient comfort. If the SPECT scan, cognitive assessment and physician evaluation show improvement after 40 treatments, another 40 HBO treatments will be administered. Treatments will be discontinued after a 40 session interval if the SPECT scan, cognitive assessment and physician evaluation show no improvement. At this time, a neurology exam will also be performed. The patient will also have a SPECT scan and cognitive assessment follow up 3 months after final HBO treatment. See Assessment Schedule listed in Table: 4.1

Because of the expected high variability on these measures for different TBI patients, the outcome of this study will be based on changes in the measures from baseline. Thus each subject serves as his/her own control. This has the further advantage of removing the need for a separate expensive and unethical control arm of this study in which healthy patients undergo the same regimen as the TBI patients, or TBI patients undergo a waiting period before starting TBI treatments. Baseline assessments must be completed not more than one year before the initial Visit 1/ to the clinic.

The primary endpoint will be improved cerebral blood flow on the SPECT scan. It is expected that most TBI will show signs of improvement within completion of 40 HBO treatments (Harch et al, 2012). The study treatment will be stopped at the patient's request, the physician's request, or if HBO cannot be continued due to medical or financial constraints.

Secondary endpoints will include improvement scores on cognitive assessment and level of disability.

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Table 4.1: Assessment Schedule:

Visit:	Baseline	Baseline	Post 40 HBO	Post 80 HBO	Post 120 HBO	3 Month Follow Up
Visit No.	**1A**	**1B**	**2**	**3**	**4**	**5**
Informed Consent	X					
Demographics	X					
Medical History	X					
Concomitant Medications	X	X	X	X	X	X
Adverse Events	X	X	X	X	X	X
Inclusion/Exclusion	X	X				
Pregnancy Test[1]		X				
SPECT Scan	X		X	X	X	X
Physical Examination		X				
Trail Making Test A and B		X	X	X	X	X
VA Cognitive Eval.[2]		X	X	X	X	X
Physician Review	X	X	X	X	X	X
Neurologist Eval.[3]					X	
HBO treatment scheduled		X	X	X		

1. To be completed by all women of childbearing potential at Baseline and again within 7 days of first HBO treatment.
2. VA Cognitive Evaluation to be completed by Principal Investigator.
3. Neurologist Evaluation to be completed after final 120 HBO treatments.

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5. Eligibility

5.1 Inclusion criteria:

Patients eligible for inclusion in this study have to fulfill **all** of the following criteria:

- All Stage TBI as demonstrated by loss of consciousness due to the injury that is at least 1 year old at the time of Visit 1. Minimum of 1 year old. TBI may include: external head injury, stroke, open head injury, hypoxic injury and diffuse axonal injury.
- Male or female patients Age ≥18 years of age at Visit 1.
- ECOG rating score 0-2
- Women: Negative pregnancy test via urine specimen required at screening for all women of child bearing potential. If sexually active, women will take contraceptive measures for the duration of the treatments. Medically acceptable contraceptives include: 1) surgical sterilization (such as tubal ligation, hysterectomy, 2) approved hormonal contraceptives (such as birth control pills, patches, implants or injections), 3) barrier methods (such as a condom or diaphragm) used with a spermicide, or 4) an intrauterine device (IUD).
- Women: Additional urine specimen for pregnancy testing is required for all women of child bearing potential within 7 days prior to first dose of HBO.
- Subject is alert and oriented x3 to give legal, effective consent.
- Written informed consent, approved by the Institutions Review Board must be obtained before any assessments are performed.
- History of lung disease (e.g. bronchitis, asthma) requires chest x-ray prior to inclusion in the study
- Documentation of TBI with a CT Scan of head , MRI of brain **or** SPECT Scan, neurological evaluation by a neurologist and primary physician within 12 months of Visit 1.
- Not taking prohibited medications

5.2 Exclusion criteria:

Patients fulfilling **any** of the following criteria are not eligible for inclusion of this study.

- Untreated Pneumothorax
- Anti-metabolites/chemotherapeutic agents (is used currently)
- History of spontaneous pneumothorax
- Seizure Disorder
- Acute Upper Respiratory Infection
- Acute High Fever
- Acute Viral Infection
- Participation in another experimental trial with active interventions
- Women who are pregnant or lactating
- History of Brain tumor (malignant or benign)
- Brain infection
- Dementia or Alzheimer's Disease
- History of malignancy (basal cell carcinoma and in situ squamous cell carcinoma of skin that has been completely excised with clear margins will be considered eligible).
- No psychiatric disorders (e.g., bipolar disorder, schizophrenia, Major depressive disorder, etc.)

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Treated depressive disorders with documented stability for 12 months prior to Visit 1 will be considered eligible.

- Any previous HBO treatment
- Any concurrent disease that may interfere with efficacy of treatment in the opinion of the Investigator.
- Currently taking any prohibited medications (See Table 5.1 below)
- Active/Open Workers Compensation Case.
- Active cardiac issues: e.g. Aortic aneurysm, Unstable ventricular tachycardia, atrial fibrillation, etc.as per PI discretion.

Table 5.1: Prohibited Medications

Prohibited Medication:	Comments:
Antiepileptic medications (e.g., Valproate, lamotrigine, carbamazeipine, phenytoin, levetiracetam, topiramate, etc.)	Use of medication for indications other than seizure control with documentation will be considered eligible.
Acetylcholinesterase inhibitors (e.g., donepezil, galantamine, rivastigmine, etc.)	Requires a wash out period of 5 half-lives prior to screening period
Memantine	Requires a wash out period of 5 half-lives prior to screening period
Anti-metabolites (e.g., methotrexate, flurouracil, etc.)	Requires a wash out period of 5 half-lives prior to screening period
Chemotherapeutic agents	Current use
Amantadine	Requires a wash out period of 5 half-lives prior to screening period

- The following are exclusions, if diagnosed in the past year, **unless** medically cleared by a physician:
    - History of thoracic surgery
    - Pneumothorax risk & CPR
    - Pulmonary lesions on X-ray or CT scan
    - Obstructive lung disease
    - Asthma
    - Congestive Heart Failure
    - Chronic Sinusitis
    - Sickle Cell Anemia
    - Reconstructive Ear Surgery
    - History of optic neuritis
    - Recent retinal repair
    - Congenital spherocytosis

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- Severe confinement anxiety
- Use of nicotine

6. Human Subject Protections

Adult subjects will be selected by the above criteria. Recruitment of patients will include word of mouth via community doctors, pamphlets and press release. All treatments will be at Jupiter Medical Center.

7. Consent Process

The Principal Investigator or designee will fully explain the purpose and potential risks and benefits of the study to the subject prior to enrollment and address any questions posed by the subject. The subject will receive a copy of the signed consent document. The original signed consent will be retained by Jupiter Medical Center's Research Department for each subject. The investigators will explain to each subject the nature of the study, its purpose, the procedures involved, the expected duration, the potential risks and benefits involved, and any discomfort it may entail. Each subject will be informed that participation in the study is voluntary and that he/she may withdraw from the study at any time, and that withdrawal of consent will not affect his/her subsequent medical treatment or relationship with the treating physician. If the consent form is amended throughout the duration of the subject's treatment, the subject who are currently active at the time of the change will be informed of the changes and asked to sign the amended consent form. A copy will be given and the original will be retained with the previous signed consent.

8. Evaluation of Benefits, Risks and Discomforts

8.1 Benefits:

Decrease in symptoms, improved cerebral blood flow, neurologic improvement in patients with TBI

8.2 Risks:

Under proper supervision, the risks of HBO treatment are very minimal. The most common side effect is ear pain, and patients are monitored closely for this. Rarely, less likely but serious, oxygen toxicity, pulmonary barotrauma, and vision change can be experienced.

The following list of potential side effects is reviewed with each patient prior to beginning therapy.

- **Otic Barotrauma** (pain in the ears or sinuses). Some patients may experience pain in their ears or sinuses. If they are not able to equalize their ears or sinuses, the pressurization will be slowed or halted and suitable remedies will be applied.
- **Serous Otitis.** Fluid in the ears sometimes accumulates as a result of breathing high concentrations of oxygen. It may occasionally feel like having a "pillow over the ear." This disappears after hyperbaric treatment ceases and often can be eased with decongestants.
- **Oxygen Toxicity**. The risk of oxygen toxicity is minimized by never exposing patients to greater pressure or longer times than are known to be safe for the body and its organs. The risk is less than one in 10,000 treatments.

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- **Visual Changes** (blurring, worsening of near-sightedness [myopia], temporary improvement in far-sightedness [presbyopia]). After 20 or more treatments, especially for those over 40 years old, some patients may experience a change in vision. This is usually temporary and in the majority of patients, vision returns to its pre-treatment level about six weeks after the cessation of therapy. It is not advisable to get a new prescription for glasses or contacts until at least eight weeks after ending hyperbaric oxygen therapy.
- **Maturing or Ripening Cataracts**. Individuals with cataracts have occasionally had a maturing or ripening of cataracts. This is not reversible and may need surgical treatment.
- **Cerebral Air Embolism and Pneumothorax**. Whenever there is a rapid change in ambient pressure, there is the possibility of rupture of the lungs with escape of air into the arteries or into the chest cavity outside the lungs. This can only occur if the normal passage of air out of the lungs is blocked during decompression. Only slow decompressions are used in HBO treatment to obviate this possibility. It is important for patients to breathe normally during treatment and not hold their breath. This is less likely, but serious.
- **Fatigue**. Some people may subjectively feel fatigue following hyperbaric treatment, but this is not a consistent finding.
- **Risk of Fire**. With the use of oxygen in any form there is always an increased risk of fire. However, strict precautions have been taken to prevent this and all applicable codes have been complied with. There has never been a fire involving a hyperbaric chamber at Jupiter Medical Center.

9. How HBO Treatment Administered

Before going into the monoplace chamber, the patient is required to remove all clothing and put on a 100% cotton gown. Once they are lying comfortably on the transfer gurney, it will be slid into the clear sided chamber. After the door closes, the gentle "hiss" of the incoming oxygen used to pressurize the chamber will be heard.

As pressure develops in the chamber, the patient will notice the chamber warming slightly. They will also feel fullness in their ears and should begin ear clearing procedures. When compression is complete, the need for ear clearing ceases. The patient may now rest, watch TV, view a video tape or listen to music. The patient will be in the HBO chamber for approximately 60 minutes at 1.5 ATA. Allowance of additional time in the chamber will be needed to account for compression and decompression.

During decompression, the chamber becomes cooler and the patient will feel a slight popping sensation in their ears as they adjust to the changing pressure. There is no need to clear the ears during decompression. No oxygen mask is required in this chamber because the entire chamber is filled with USP medical grade oxygen.

10. Contraindications to HBO Treatment

Two contraindications to HBO treatment are an untreated tension pneumothorax (an accumulation of air or gas in the pleural cavity of the lungs) and certain chemotherapy agents. Chest X-rays will be performed prior to initial treatment.

There are several conditions in which caution must be observed. It is important that the hyperbaric physician is aware of the following conditions prior to beginning treatment:

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Chronic sinusitis
Congenital spherocytosis
Emphysema with C02 retention
History of optic neuritis
History of reconstructive ear surgery
History of spontaneous pneumothorax
History of thorax surgery
Pulmonary lesions in routine X-ray or CT scan
Seizure disorders
Sickle cell anemia

11. Early Study Termination

The Investigator must promote compliance to treatment schedule by instructing the subject to complete each HBO treatment exactly as designed in the protocol by stating that compliance is necessary for the validity of the study. The subject must also be instructed to contact the Investigator if he/she is unable to complete a treatment for any reason. If a subject cannot complete a treatment due to an adverse event, the Investigator will determine whether the subject should continue or be terminated from the trial. If a subject misses more than 5 consecutive treatments, the Investigator will determine whether or not to terminate the subject from the trial.

12. Compensation

There will be no compensation given to participants in this study.

13. Efficacy Assessment

Monitored by SPECT scan, Trail Making Test Part A and B (See in Appendix 1), Evaluation of Cognitive Impairment (4.124a - Schedule of ratings - neurological conditions and convulsive disorders, United States Department of Veteran Affairs, 2012) completed by the Principal Investigator (See Appendix 2).

14. Safety Assessment (including recording adverse events)

The investigator will assess for adverse events at each treatment.
Serious adverse events (SAE) are to be reported to FDA utilizing MEDWatch form FDA 3500A.

An SAE is defined as death or a life threatening event, permanent impairment or an event that requires medical or surgical intervention to preclude impairment.

All adverse events (AE) will be recorded by Jupiter Medical Center's Research Department. All AEs will be documented using CTCAE v4 criteria with grade and attribution. Any SAE will be reported to the IRB as requested/required.

An independent Clinical Research Organization (CRO) will monitor all data, regulatory documents, and compliance with AE reporting throughout the study. In addition, interim analyses will be performed after 25% accrual has been reached.

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15. Statistical Analysis

Statistics will be documented to identify improvement.

The Trail Making Test (TMT) uses an objective scoring method based on time that offers validity to cognitive performance status. “Results for both TMT A and B are reported as the number of seconds required to complete the task; therefore, higher scores reveal greater impairment” (Trail Making Test (TMT) Parts A & B (See Appendix 1)).

The Veterans Administration Evaluation of Cognitive Impairment and Other Residuals of TBI will also be used to determine extent of improvement (4.124a - Schedule of ratings - neurological conditions and convulsive disorders, United States Department of Veteran Affairs, 2012 (See Appendix 2)).

SPECT CT blood flow analysis will be performed consistently on the same machine and interpreted by the same investigator or designee to increase objectivity. An increase in the number of pixels on the SPECT scan will indicate improved blood flow to the brain.

The objective measure will be the Trail Marking Test. We will compute the fraction of patients who show improvement on the Trail Marking Test. If a sample of patients were taken without treatment we would expect about half to improve on the TMT and about half to get worse. For the treated patients we will test the hypothesis that the population fraction improving is larger than 0.5 against the alternative that is it 0.5 (a one-sided test). The binomial distribution will be used to perform the test and obtain confidence intervals. Other measures will be summarized by the average and confidence intervals for the change from baseline using appropriate t-distributions.

16. Expected Outcomes

Improved (increase number of pixels on SPECT scan) blood flow to brain, improved (cognitive assessment score) cognitive function, improvement in symptoms and Evaluation of Cognitive Impairment score.

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17. References

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ECOG Performance Status*

These scales and criteria are used by doctors and researchers to assess how a patient's disease is progressing, assess how the disease affects the dally living abilities of the patient, and determine appropriate treatment and prognosis. They are indicated for health care professionals to access.

Grade 0 = Fully active, able to carry on all pre-disease performance without restriction

Grade 1= Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g. light housekeeping, office work

Grade 2 =Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours

Grade 3 =Capable of only limited self-care, confined to bed or chair more than 50% of waking hours

Grade 4 = Complete disabled. Cannot carry on any self-care. Totally confined to bed or chair

Grade 5 = Dead

*As published in AM. J. Clin. Oncol.:

Oken, M.M., Creech, R.H., Tormey, D.C., Horton,1., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am 1Clin Oneal 5:649-655, 1982.

The ECOG Performance Status is in the public domain therefore available for public use. To duplicate the scale, please cite the reference above and credit the Eastern Cooperative Oncology Group, Robert Comis, M.D. Group Chair.

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