Combating PTSD

Through Integrated Stellate Ganglion Block Treatment & Neuro-Training Protocols

Component 1: Stellate Ganglion Block Injection

Discovery of Nerve Pathway Involved with PTSD

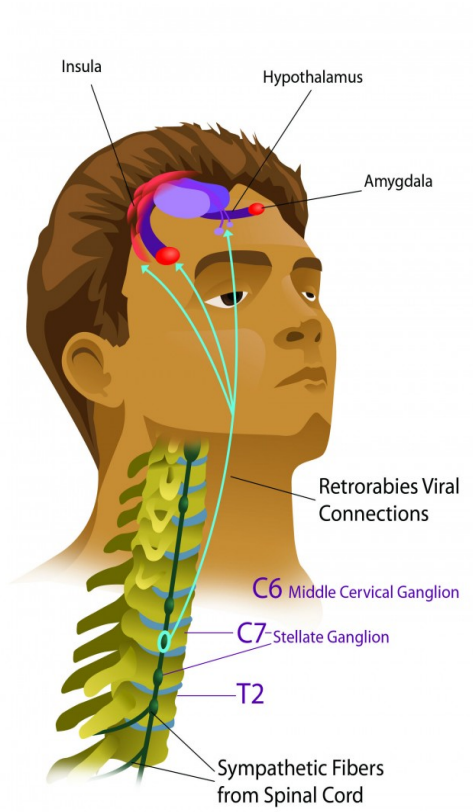
Dr. Eugene Lipov is the person who discovered the rapid and long-lasting benefits of the Stellate Ganglion Block injection for Post Traumatic Stress Disorder (PTSD). This treatment has been utilized since 1925 in order to block pain signals from reaching the brain (i.e. chronic pain treatment). However, it was not until 2005 that Dr. Lipov discovered the treatment's capacity to provide rapid and long-duration relief from PTSD symptoms. Typically, patients have relied upon SSRIs and Benzodiazapines in conjunction with psychodynamic therapies for PTSD, but the results have been minimal, because they do not effectively address CNS dysregulation, the origin of the problem. Therefore, many have called for new strategies to address these symptoms with increasing urgency.

The mechanism of action is believed to be related to the injection's capacity to down-regulate arousal of the bottom-right amygdala, a region of the brain that is over-active in PTSD cases. Through administering the very well tolerated and low risk injection, this nerve pathway's excitatory response is suppressed, and the amygdala's over-arousal is rapidly mitigated.

Documented Clinical Results

Since his discovery, Dr. Lipov has personally treated an estimated 550 patients, while 200 of those were veterans, and 30 have been soldiers. Through his private practice, he has observed an 80% (est) recovery rate with no relapse when patients received follow-up assessments 3 – 6 months after treatment, and his longest documented success has persisted for 9-years. This represents a profound and unprecedented opportunity to further research the benefits of this treatment for veterans with PTSD. Moreover, Dr. Lipov has recently patented what he believes to be a more effective version of the active ingredient's primary chemical, and he believes that the results could grow to 85 – 90% efficacy.

Through combining this with real-time brain monitoring and neurofeedback self-regulation training, the results could be further enhanced through training veterans in CNS self-regulation.



Congressional Testimony & News Publications

Dr. Lipov's work appears in his congressional testimony (2010), where he explains why he believes this method should be explored. This method has also been featured on a growing number of news publications such as the Wall Street Journal, Military Times, ABC, Fox News, and others, resulting in growing interest in researching this intervention.

Recent Pentagon Funded Research

The Department of Defense has funded a $2Million FDA Phase IIa trial, and treatments have been provided to patients at Ft. Bragg, the Long Beach Veterans Administration, Womack Army Medical Center, Tripler Army Hospital, the Naval Hospital in San Diego, CA, as well as the Army's Landstuhl military hospital in Germany.

FDA Status & Restrictions

FDA Phase IIa clinical trials are in progress with Pentagon funding, and the principal investigator is Bradford B Walters, MD, PhD, MBA. However, the treatment may be administered without FDA approval so long as this is administered by a Medical Doctor. Dr. Lipov believes the Federal Government will be comfortable authorizing a treatment program with the current regulatory permissions that exist. The total cost of each treatment is approximately $2,000, which represents a significant reduction in cost of care in relation to conventional therapies.

The potential risks have been well researched, and after 45,000 people have been treated for other conditions with this injection protocol, 99.952% of individuals did not experience side-effects. Thus far, there has been a very low incidence of seizure, air in the lungs, or allergic reaction in 0.024%, .02%, and .004% of the population, respectively. Meanwhile, VA's more commonly used second generation antipsychotics double the risk of cardiac death and are nearly 15x more side-effect prone.

Pending Studies

FDA Clinical Study (2018)

RTI International

Publications

Publication: VA Literature Review (2017)
Authors: Kim Peterson, MS, Donald Bourne, BS,
Johanna Anderson, MPH, Katherine Mackey, MD,
and Mark Helfand, MD, MS, MPH.

Publication: Department of Veteran Affairs (2017)
Author: VA Evidence Based Synthesis Program.
Mark Helfand, MD, MPH, MS, Director

Publication: Johns Hopkins (2016)
Mary R. Summers, MSc, MHS*; Remington L. Nevin, MD, MPH, DrPH

Publication: Anesthesiology (Annual Meeting) (2015)
Authors: Michael T. Alkire, M.D., Michael Hollifield, M.D.,
Rostam Khoshsar, M.D., Linda Nguyen, M.P.H.,
Stephanie R. Alley, M.A., Christopher Reist, M.D.
Long Beach VA Healthcare System and
Univ of California, Irvine, California, United States

Publication: Journal of Trauma and Treatment (2014)
Author: Dr. Eugene Lipov

Publication: Review of Cases (2014)
Authors: Maryam Navaie, Morgan S. Keefe,
Anita H. Hickey, Robert N. McLay,
Elspeth Cameron Ritchie, Salahadin Abdi

Military Treatment Locations

Long Beach Veterans Administration (2017)

Tripler Army Hospital (2017)

Naval Hospital in San Diego, CA (2017)

Army Landstuhl Military Hospital (2016)

News Reports:

News Report: PTSD Animal Case Study (2018)

News Report: Wall Street Journal (2017)

News Report: Army.mil (2017)

News Report: The Desert Sun (2017)

News Report: ABC 10 (2017)

Press Release: PTSD & Army Captain (2017)

News Report: WSOC Charlotte (2017)

News Report: Sacramento Bee (2017)

News Report: Daily Mail, Army Investment (2017)

News Report: 'Task & Purpose' Call for Volunteers (2016)

News Report: 'Stars & Stripes' Call for Volunteers (2016)

News Report: Military Times (2014)

News Report: Waterloo Cedar Falls Courier (2013)

News Report: Quincy Herald Whig (2013)

News Report: Fox News (2012)

News Report: Popular Science (2011)

News Report: Chicago Tribune (2010)

News Report: Wired News, Obama (2010)

News Report: ABC News (2010)

News Report: Chicago Daily Herald (2010)

PR: Walter Reed Report (2010)

Dr. Lipov Content (Video)

Congressional Testimony (2010)

Summary (2013)

PTSD Mechanism (2013)

Television Features (Video)

Television Show: Mlitary Sexual Trauma (2017)

Television Show: Mass Shooting Survivor (2017)

Television Show: Patient Success Stories (2014)

Jason Brown Case Study (Video)

Jason Brown, Injection 1 (Video) (2008)

Jason Brown, Injection 2 (Video) (2009)

Jason Brown, Injection 3 (Video) (2010)

Current FDA Data Analysis (Phase IIa)

Primary Contact: Bradford B Walters, MD, PhD, MBA

Official Title: A Randomized, Sham-procedure-controlled, Blinded Study to Evaluate the Effectiveness and Acceptability of Right-sided Stellate Ganglion Block for Treatment of Posttraumatic Stress Disorder Symptoms – Acceptability

Summary: "This qualitative study will use focus groups, small group interviews, and individual interviews (both in person and over the phone) to compile a range of perspectives on service members' decision-making processes and information needs related to Stellate Ganglion Block (SGB). Participants will include service members, spouses, and providers.

Study Details

Study Type :	Observational
Actual Enrollment :	54 participants
Observational Model:	Other
Time Perspective:	Retrospective
Actual Study Start Date :	November 3, 2017
Actual Primary Completion Date :	March 2, 2018
Actual Study Completion Date :	March 2, 2018
Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Participants

Service members who received at least one SGB study procedure as part of the clinical effectiveness trial during the three months prior to qualitative data collection or service members who received at least one SGB for PTSD symptoms at a study site in the three months prior to qualitative data collection.

Study Population: Participants in effectiveness clinical trial and their spouses service members who have received SGB for PTSD symptoms at the participating study sites outside of the clinical trial and their spouse providers who have referred or could potentially have referred patients for SGB for PTSD symptoms at the study sites clinicians who provide SGB for PTSD.

Inclusion criteria:

1. Service members must have received at least one SGB and/or study procedure for PTSD symptoms during the past three months at a participating study site (as a participant in the clinical effectiveness trial or outside of the study).
2. Clinical trial participants must have indicated willingness to participate in the qualitative study when asked by the Research Coordinator (RC) at baseline data collection.
3. Non-clinical trial participants must be active-duty status.
4. A service member/spouse dyad will consist of a service member meeting an above criterion and his/her spouse.
5. Providers will be Behavioral Health or other (e.g., Family Medicine) clinicians who have referred or could potentially have referred service members to the study, and physicians who administer SGBs.

Exclusion Criteria:

Service members will be excluded from the qualitative study if participation would cause them undue distress, in the opinion of the RC or treating clinician.

Primary Outcome Measures :

1. Participants' perceptions of SGB in relation to other options for treatment of PTSD, from the perspectives of service members or service member/spouse couples. [Time Frame: Within three month of receiving one SGB study procedure for PTSD symptoms]
   Discussion topic areas:
   - Context for mental health and treatment
   - Advantages and drawbacks of treatment options
   - Information and decision-making
   - Experience and expectations"

Letters of Support

DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 SCOTT STREET
FORT DETRICK, MD 21702-5012

REPY TO
ATTENTION OF

September 15, 2010

Eugene Lipov, M.D.
Advanced Pain Center, S.C.
2260 West Higgins Road
Hoffman Estates, Illinois 60169-2431

Dear Dr. Lipov:

I am writing as a follow-up to the phone conference held on September 14, 2010, regarding your proposed research study, "Placebo-Controlled Study of Stellate Ganglion Block to Relieve Posttraumatic Stress Disorder in Military Personnel". This study has the potential to significantly impact in the treatment of PTSD in military servicemembers.

The Military Operational Medicine Research Program (MOMRP) is interested in supporting this study contingent upon availability of funding and collaboration with others organizations to assist in the recruitment of military subjects for your initial study.

If you have any further questions please contact me at 301.619.7304 or at Carl.Castro@us.army.mil.

Sincerely,

Colonel Carl A. Castro
Director, MOMRP

Congress of the United States
Washington, DC 20515

November 15, 2007

Ms. Pamela Fisher
Contracting/ Grant Officer
Department of the Army
US Medical Research Acquisition Activity 820 Chandler Street Fort
Detrick, MD 21702 - 6014

Dear Ms. Fisher:

As members of the Illinois delegation, we write in support of the grant application submitted by Dr. Eugene Lipov entitled, "Proposal to Conduct a Two-Part Study on Stellate Ganglion Block and Pulsed Radio Frequency to Relieve Post Traumatic Stress Disorder in Military Personnel." This proposal seeks to further the research and treatment of Post Traumatic Stress Disorder (PTSD).

As you are aware, reports suggest that PTSD is affecting a growing number of soldiers returning from combat in Iraq and Afghanistan, as well as soldiers from previous theatres of combat. These brave men and women have served our nation heroically and deserve the best care available. As Members of Congress, we are committed to providing the necessary resources to improve screening and treatment of PTSD. We also believe it is important to consider any new approaches that may prove useful in assisting our active and retired service members.

For this reason, we ask that you consider the grant application submitted by Dr. Lipov. Dr. Lipov and his research team propose to conduct a two-part clinical study on a new treatment method to alleviate anxiety and other symptoms of PTSD in conjunction with standard treatment practices. This study has the potential to provide an innovative and effective remedy for our returning soldiers who are suffering from PTSD.

While we leave the final decision to your selection committee, thank you for your time and consideration of this matter as well as your continued commitment to the health of our military personnel.

Sincerely,

Dan Lipinski
Member of Congress

Rahm Emanuel
Member of Congress

Phil Hare
Member of Congress

United States Senate

WASHINGTON, DC 20610

November 15, 2007

Ms. Pamela Fisher
Contracting/ Grant Officer
Department of the Army
US Medical Research Acquisition Activity
820 Chandler Street
Fort Detrick, MD 21702 - 6014

Dear Ms. Fisher:

We are writing to request that the Department of the Army consider the application, "Proposal to Conduct a Two-Part Study on Stellate Ganglion Block and Pulsed Radio Frequency to Relieve Post Traumatic Stress Disorder in Military Personnel," submitted by Dr. Eugene Lipov and supported by Northwest Community Hospital in Illinois. This application proposes research into potential new treatment methods for Post-Traumatic Stress Disorder (PTSD).

As you know, there is a growing body of evidence to suggest that PTSD is affecting a growing number of our heroic service members returning from Iraq and Afghanistan. We have both worked in the Senate to strengthen the quality of mental health care provided by the US Armed Forces and the Veterans Administration (VA), and we continue to support important new investments in the screening and treatment of PTSD and Traumatic Brain Injuries (TBIs). We believe that PTSD and other forms of combat stress, anxiety and depression will require ongoing support and counseling for those with such diagnoses as well as their loved ones. At the same time we believe it is important to consider any new approaches that may hold potential for helping our service members get the care they need.

While we leave the evaluation of the merits of this particular proposal to the judgment of the selection committee, we appreciate your ongoing commitment to improving mental health care for our service members.

Sincerely,

Barack Obama
United States Senator

Richard Durbin
United States Senator