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TITLE: Prospective Cohort Study of Stellate Ganglion Block for Treatment of Post-Traumatic Stress Disorder Symptoms and Other Non-Pain Conditions

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14. ABSTRACT

This study seeks to follow for a period of 1 year all Service members and Veterans at five military treatment facilities who receive stellate ganglion block (SGB) for treatment of Post-Traumatic Stress Disorder (PTSD) or other non-pain conditions. Up to 300 consenting individuals will be enrolled into the cohort; enrollment will last for 18 months. Assessments will be conducted at baseline and at 2, 4, 6, 9, and 12 months. Outcomes will include symptom trajectory for PTSD and other conditions, changes in neurocognitive functioning, and changes in sleep quality and structure.

15. SUBJECT TERMS

Stellate ganglion block, Post-Traumatic Stress Disorder, prospective cohort

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1. Introduction

This study will follow up to 300 consenting Service members, Veterans, and retirees at any of the following five study sites: Womack Army Medical Center (WAMC; Fort Bragg, NC), Tripler Army Medical Center (TAMC; Honolulu, HI), Landstuhl Regional Medical Center (LRMC; Landstuhl, Germany), Walter Reed National Military Medical Center (WRNMMC; Bethesda, MD), and Brooke Army Medical Center (BAMC; Fort Sam Houston, TX). Participants already scheduled to receive stellate ganglion block (SGB) for treatment of Post-Traumatic Stress Disorder (PTSD) or other non-pain conditions will be followed for 1 year and assessed at baseline as well as at months 2, 4, 6, 9, and 12. Data collection will take place for 18 months. Outcomes will include symptom trajectory for PTSD, depression, anxiety, and other conditions; changes in neurocognitive functioning; and changes in sleep quality and structure.

2. Keywords

Stellate ganglion block, Post-Traumatic Stress Disorder, prospective cohort

3. Accomplishments

The major goals of this project for year 1 focused on the U.S. Army Medical Research and Materiel Command's regulatory (i.e., clinical protocol and Institutional Review Board [IRB]/ Human Research Protection Office [HRPO]) activities, development of study infrastructure (i.e., development and testing of data collection platforms, and programming of assessments), and coordination with co-investigators at the five study sites.

During year 1, the study team drafted the IRB packages; however, we experienced significant challenges in identifying the appropriate way to submit the packages given changes made in the process. We were able to clarify the correct IRB process in quarter 4 of the performance period.

Also during year 1, the team coordinated with co-investigators and drafted the study protocol (to be submitted with IRB and HRPO packages). In addition, we communicated regularly with co-investigators to apprise them of the study's status.

The team completed all programming and testing of web control systems and instruments and developed the website (https://sgbcohort.rti.org/) in year 1.

Task 1: Conduct Cohort Study (Months 1-36)		
Subtask 1: Prepare Regulatory Documents and Research Protocols		
Milestone	**Complete?**	**Comments**
Finalize Study Protocol	Yes	
Receive Common Access Cards	No	Determined to be unnecessary
Receive All IRB and HRPO Approvals	No	To be submitted in quarter 1 of year 2
Subtask 2: Develop Study Infrastructure		
Milestone	**Complete?**	**Comments**
Finalize Data Platforms	Yes	Completed early
Hire and Train Research Coordinators	No	Not yet needed
Milestone	**Complete?**	**Comments**

Finalize Web Control Systems and Instruments	Yes	Completed early

For the upcoming project year (i.e., year 2), we anticipate receiving IRB and HRPO approval (IRB package to be submitted in quarter 1 of year 2). We will also hire and train Research Coordinators unless we are unable to begin data collection due to coronavirus 2019 (COVID-19) restrictions.

4. Impact

Nothing to report.

5. Changes/Problems

Changes: Nothing to report.

Problems: During year 1, we had difficulty identifying the proper procedures for submitting the study IRB package, which have changed significantly since we submitted the package for the original SGB study. In quarter 4 of year 1, we established the proper procedures, and we will submit the IRB package in quarter 1 of year 2. Upon approval, we will submit the package to HRPO.

We anticipate that travel restrictions due to COVID-19 will affect our data collection timeline.

6. Products

Study website: https://sgbcohort.rti.org/

Study data collection and control system platforms

7. Participants and Other Collaborating Organizations

The following individuals have worked on the project for a minimum of 160 hours during project year 1. There has been no change in support of the Principal Investigator, co-investigators, or key personnel, and no other organization was involved as a partner.

Name	Project Role	Person Months Worked	Contribution to the Project
Rae Olmsted, Kristine L.	Principal Investigator	4.7	Daily study operations; management and substantive oversight (IRB/HRPO submissions, budget, substantive materials)
Zemonek, Richard D.	Computer Programming Task Leader	3.0	Oversight of all computer programming activities (web and assessment programming, co-design of the control system, quality control for all systems)

8. Special Reporting Requirements

Not applicable.

Appendix A: Study Quad Chart

Prospective Cohort Study of Stellate Ganglion
Block for Treatment of Post-Traumatic Stress Disorder Symptoms and Other Non-Pain Conditions
W81XWH2020011

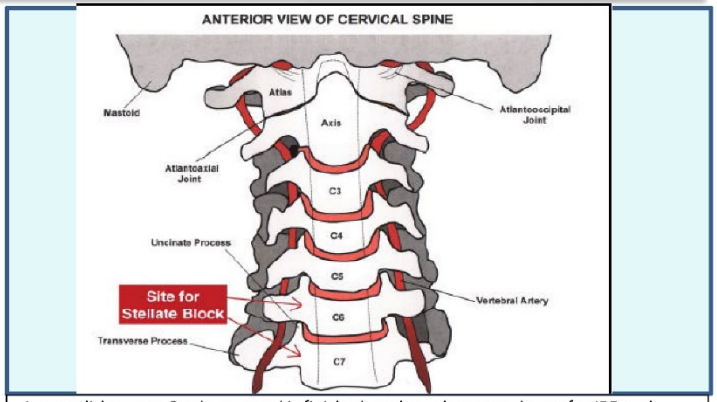
PI: Kristine Rae Olmsted **Org:** RTI International **Award Amount:** $4,592,921

Study/Product Aim(s)

- For how long after SGB are symptoms of PTSD and other disorders (anxiety, depression, sleep difficulties, tinnitus) decreased?
- Are neurocognitive or performance impacts associated with SGB?
- What role does the number of SGB play in symptom trajectories?
- Does the type of traumatic exposure among those with PTSD symptoms affect SGB treatment outcomes?
- What role does time elapsed since traumatic exposure/onset of PTSD symptoms play in symptom reduction by SGB?
- Do ADSM, veterans, and retirees respond differently to SGB?

Approach

A prospective cohort study to characterize intermediate-term effects of SGB on selected physiological and psychological/behavioral characteristics of eligible active-duty Service members, veterans, and retirees receiving SGB at any of five study sites. We will follow individuals treated with SGB for PTSD symptoms and other non-pain conditions to determine the duration of effect of the treatment, impact of SGB for conditions other than PTSD (such as anxiety and tinnitus), potential neurocognitive and performance impacts associated with SGB, and the degree to which time elapsed since traumatic exposure plays a role in symptom change after SGB.



Accomplishments: Study protocol is finished, and regulatory packages for IRB and HRPO are nearly complete. All websites, control systems, and assessments have been programmed.

Timeline and Cost

Activities	Y1	Y2	Y3	Y4	Y5
Prepare Regulatory Documents and Research Protocols					
Develop Study Infrastructure					
Collect, Analyze, Disseminate Data					
Estimated Budget ($k)	**$419k**	**$1.7m**	**$1.2m**	**$900k**	**$500k**

Updated: September 2021

Goals/Milestones

Y1 Goals – Prepared regulatory packages and study protocol
Y2 Goals – Developed control systems; To be completed: submit IRB and HRPO packages; hire and train research coordinators; begin recruitment and enrollment
Y3 Goals – Continue recruitment and enrollment
Y4 Goals – Complete recruitment and enrollment; prepare data for analysis
Y5 Goals – Continue to prepare data for analysis; analyze data and disseminate findings

Comments/Challenges/Issues/Concerns

- COVID-19 could affect timeline if travel restrictions remain in place.
- Project is behind in submitting regulatory packages and protocol; anticipate submitting in quarter 1 of year 2.

Budget Expenditure to Date
Projected Expenditure: $341,623
Actual Expenditure: $295,834