



## Technical Inquiry 2019-5255

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# HDIAC



Homeland Defense & Security  
Information Analysis Center

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## Overview

A member of the U.S. Army Medical Material Development Activity (USAMMDA) requested information on potential Food and Drug Administration (FDA)-approved products, devices, or pharmaceuticals that could be used to prevent or reduce the risk of traumatic brain injury (TBI)—including mild, moderate, or severe TBI.

## Findings

HDIAC identified the very limited number of products currently being developed for the prevention or reduction of the effects from a TBI. Relevant information, including primary point of contact, email, phone number, and a brief description of the solutions is provided below.

### ***Copenhagen Head Injury Ciclosporin (CHIC) Study: A Phase IIa Safety, Pharmacokinetics, and Biomarker Study of Ciclosporin in Severe Traumatic Brain Injury Patients [1]***

|   |                            |
|---|----------------------------|
| Performing Organization: University of Copenhagen               | Primary POC: Jesper Kelsen |
| Email: <a href="mailto:jkelsen@hum.ku.dk">jkelsen@hum.ku.dk</a> | Phone: N/A                 |

**Description:** Researchers from the University of Copenhagen studied the efficacy of NeuroSTAT, a counter-TBI drug, on patients. NeuroSTAT targets the mitochondria and is meant to counteract the emergence of neurological and functional secondary brain damage after a TBI. In this Phase II clinical study of safety, tolerability, and pharmacokinetics, NeuroSTAT demonstrated favorable properties by using two different doses of ciclosporin, the primary active ingredient in NeuroSTAT [1]. Analysis of brain cell damage biomarkers in samples from patients indicated success in countering primary TBI mechanisms in the brain after a concussive event. Due to its potential effectiveness, this drug has been given a “fast track” designation from the FDA [1].

### ***Analysis of Head Impact Exposure and Brain Microstructure Response in a Season-Long Application of a Jugular Vein Compression Collar: A Prospective, Neuroimaging Investigation in American Football [2]***

|   |                               |
|---|-------------------------------|
| Performing Organization: Cincinnati Children’s Hospital             | Primary POC: Dr. Gregory Myer |
| Email: <a href="mailto:Greg.Myer@cchmc.org">Greg.Myer@cchmc.org</a> | Phone: N/A                    |

**Description:** Researchers from Cincinnati Children’s Hospital conducted a study of the effectiveness of a jugular vein compression collar in American Football players throughout an entire season. This collar is a new approach for the possible internal safety of the brain against repetitive head impacts. In the study, statistical significance was shown in preventing diffusion changes after an entire season of repetitive head impacts in high school football players [2]. This study supports the hypothesis that protecting the brain internally via jugular vein compression could be a viable option in preventing and mitigating potential TBI from repetitive head impacts [2].

## Conclusion

HDIAC identified two solutions that could potentially address USAMMDA needs for FDA-approved products for TBI prevention. A more comprehensive analysis of scar tissue release methodologies is available through an HDIAC Core Analysis Task, which would involve coordination with leading industry representatives and prototype development of leading technology candidates.

**We request your feedback on this Inquiry:** <https://www.hdiac.org/new-inquiry-assessment-form/>

## References

1. Kelsen, J., Karlsson, M., Hansson, M., Yang, Z., Fischer, W., Hugerth, M., Nordstrom, C.,...Elmer, E. (July 2019). Copenhagen Head Injury Ciclosporin (CHIC) Study: A phase IIa safety, pharmacokinetics, and biomarker study of ciclosporin in severe traumatic brain injury patients. *Journal of Neurotrauma*. DOI: 10.1089/neu.2018.6369
2. Myer, G., Yuan, W., Foss, K. D., Thomas, S., Smith, D., Leach, J., Kiefer, A.W.,...Altaye, M. (September 2016). Analysis of head impact exposure and brain microstructure response in a season-long application of a jugular vein compression collar: A prospective, neuroimaging investigation in American football. *British Journal of Sports Medicine*. <http://dx.doi.org/10.1136/bjsports-2016-096134>