STUDY TITLE: Novel protection against potential brain, hearing and vision injury during Blast Wave Exposure

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ADULT SUBJECT CONSENT FORM

STUDY TITLE: Novel protection against potential brain, hearing and vision injury during Blast Wave Exposure

STUDY NUMBER: **2016-7948**

FUNDING ORGANIZATION: Q30 Sports Science, LLC

Gregory D. Myer, PhD
Name of Principal Investigator

(513) 803-1636
Telephone Number

INTRODUCTION

We are asking you (and up to about 99 other people) to be in a research study so that we can learn new information that may help others. If you decide not to be in this study, we will still take good care of you. If you decide to be in this study, you may change your mind at any time during the study and you can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to be in the study. You can ask questions at any time.

WHY ARE WE DOING THIS RESEARCH?

In this research study we want to learn more about a new device, presently called the "Q collar (see Figure below), which may help prevent brain injury/concussion related to blast wave exposure. The neck collar device is made of soft fabric, plastic, and silicone, over a gentle embedded metal "spring" that is fitted around the neck providing comfortable compression to two of the veins on the side of the neck. We are testing the theory that this mild compression will help prevent brain related injury/concussions by back-filling the empty space around the brain with some blood and thereby acting like "bubble wrap" around it. It has been suggested that many "head banging animals" may be using a similar protection in the wild.

In addition we wish to learn more about how the brain responds to blast wave exposure during breaching and diversionary device scenario training.

We are asking you and other people like you that participate in tactical training to be in the research, because we want to learn more about how well the device works in preventing brain injury/concussions. We have successfully completed similar studies in ice hockey, football, and soccer athletes.

WHO IS IN CHARGE OF THE RESEARCH?

Greg Myer, PhD is the researcher at Cincinnati Children's Hospital Medical Center (CCHMC) that is in charge of this study. CCHMC is being paid by Q30 Labs, LLC to do this study. In addition to conducting this research study, Gregory Myer is also paid for providing scientific advisory and consulting services for the company that manufactures the device being studied in this research.

WHO SHOULD NOT BE IN THE STUDY

You cannot be allocated to the collar group if you have any of the following:

- History of neurological deficits or severe head trauma
- Known increased intracerebral pressure, metabolic acidosis or alkalosis
- Any known increased pressure in eyes
- any known increased fluid on the brain
- Recent penetrating brain trauma (within 6 months)
- Known increased pressure in the brain
- Any known blood clots to the brain
- Any known airway obstruction

WHAT WILL HAPPEN IN THE STUDY?

The research staff will explain each visit to you and may give you a handout that explains each visit in more detail. You will be able to ask questions to make sure that you understand what will happen.
If you qualify and decide you want to be in the study, you will come to CCHMC two times. Each study visit will be split into two sessions and each session will take up to 2 hours to complete.
If you are assigned to the device-wearing group, you will wear the Q collar during your tactical training that will fit around your neck which will place light pressure on your neck. While most do not find this uncomfortable, the pressure on your neck will feel like wearing a necktie. The neck collar device is made of plastic, silicone, metal and fabric that is fitted to the neck providing comfortable pressure around the neck. Studies have shown that there is no significant change in blood flow pattern or oxygen uptake pattern or any negative cognitive effect to the brain (even with prolonged similar physiology of wearing of a tight necktie) and therefore the risk of wearing this device is low. It has also been tested during high intensity exercise and has shown no effect on performance, and has been deemed safe.

This device is ONLY to be used during the tactical training. This device will NOT go home with you.

These are the things that will happen to you while you are in the study:

1. Neck Circumference Measurement: We will measure the circumference of your neck with a measuring tape. We will confirm the fit of the collar with an ultrasound test.
2. Hearing Testing: This test will place an earplug in your ear that is a recording microphone that picks up the emission coming back from the inner ear. Testing will occur without pressure and then with pressure. This research is being done to see if changes occur in the inner ear

following activation of the protective. If this is found to be possible this technology might be helpful to make sure the device is activated when it is put on for protection against concussions.

3. EEG testing: An EEG (electroencephalogram) is a test that detects electrical activity in your brain using small, flat discs (electrodes) attached to cap (like a shower cap) that you will wear on your head. Your brain cells communicate via electrical impulses and are active all the time, even when they're asleep. This activity shows up as wavy lines on an EEG recording. This portion will involve four different tests. You will not feel anything during this test.
4. MRI Imaging: You will be asked to lie down in a machine that will take images of your brain. For part of this test, you may be asked to lay still. For other parts of this test, you may be asked to answer questions that will assess his/her thinking and memory. This test will be completed at the pre-season and post-season time points during a separate session from the tests described above and will take approximately 60 minutes to complete. Prior to the imaging appointment, you will be asked to complete a screening questionnaire to ensure that you does not have any contraindications to this type of scan. If any contraindications are revealed (i.e. permanent metal dental/orthodontic work, cochlear implant, cardiac pacemakers, orthopedic pins/screws/plates, etc) you will not complete the MRI imaging portion of this study. This will not affect your participation in the remaining parts of this project.
5. Accelerometers: An accelerometer is a device that measures how fast something is moving. You will be fitted with two accelerometers to wear during the tactical training (one in your helmet and one placed behind your ear).

Group Assignment: You will be assigned to one of two groups1) Subjects wearing the Q-collar device (seen in Figure on page 1) around the neck or 2) Subjects not wearing the Q-collar device. Both groups will complete the same testing and training as all participants in the study. To ensure proper fitting of the collar, ultrasound will be utilized. All breacher exercises will be videotaped for research purposes.

WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

Being in this study may not help you right now. When we finish the study, we hope that we will know more about this device and its effectiveness in preventing brain injury/concussions. This may help us prevent brain injury/concussions later on. We do not currently know if this device will protect you from suffering a concussion injury.

WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

There are no known risks of wearing the Q collar device. There are no known negative effects from exposure to the magnet or radio waves used in the MRI at this time; however it is possible that harmful effects could be recognized in the future. The tight space of the MRI may make some people feel uncomfortable. One known risk is that the magnet can attract certain kinds of metal. Therefore, we will have all subjects complete a pre-MRI screening questionnaire. If there is any indication from this questionnaire that the MRI is not safe you will not have the MRI testing. The MRI testing will require you to lie on your back and remain still for the duration of the test, which could last about 60 minutes. Due to the nature of the test, there will be a loud knocking noise that you will hear while the test is being performed. You will be instructed that if at any point during the test, you can signal to the research staff to stop the test if you get too uncomfortable.

The risks that are normally associated with standard breacher training include exposure to blast waves including risk of blast injury, hearing and potential for concussive blasts. The risks are mitigated by using standardized protective equipment, highly trained breacher staff as well as strict adherence to training guidelines. It is unknown how wearing the collar may or may not change the risks of this standard training exercise. The risks strictly from the breacher exercise are not research related. But, wearing the collar may change those risks. Any injury that occurs from the breacher training is not the responsibility of the research study.

There is also a minimal risk that the data collected may be viewed by individuals outside the research team. The risk that confidential data may be viewed is relevant for both the written forms and the electronic databases.

There may be other risks that we do not know about yet.

WHAT OTHER CHOICES ARE THERE?

Instead of being in this study, you can choose not to be in it. Participating in this research is completely voluntary. You will not be punished if you decide not to participate.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE?

Making sure that information about you remains private is important to us. To protect your privacy in this research study we will: keep the results of this study confidential. No subject identification will be made public record in any form unless you give your expressed written permission of release of your name, photograph or likeness captured on video. You have the right to privacy. We will protect your privacy to the extent allowed by law. All facts about this study that can describe a subject's name will be kept private. Results of the study will be summarized regarding age, etc., but we will take every precaution necessary to keep names private. All subject data will be blinded from the researchers with the use of an identification code. Personal information and identifiers will be securely recorded and filed by the administrative assistant. The data will be encrypted with a password and stored on a personal computer and backed up on a network drive. We will be available for any questions that might arise.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the study results. You can search this website at any time.

Because this research study involves payment for participation we are required by federal Internal Revenue Service (IRS) rules to collect and use your social security or tax ID number (SSN) in order to track the amount of money that we pay you. Unless you have given specific permission for another use of your SSN related to this research we will only use your SSN to keep track of how much money we pay you and your SSN will not be used as part of this research.

The Food and Drug Administration (FDA) may choose to inspect your records since you are a subject in this investigation of an unapproved device.

WHAT IF WE LEARN NEW INFORMATION DURING THE RESEARCH?

The study doctor will tell you if they find out about new information from this or other studies that may affect your health, safety or willingness to stay in this study.
The MR imaging that you are having as part of this research study will be reviewed by a qualified radiologist just as it would be if you were having the MRI as part of your routine medical care. There is a possibility that while reviewing your MRI we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding." We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by mail or by phone. If you want, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation. The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

WILL IT COST YOU ANYTHING EXTRA TO BE IN THE RESEARCH STUDY?

Participating in this study will not cost you anything other than time and effort. Your insurance will not be billed for any testing associated with this study.

WILL YOU BE PAID TO BE IN THIS RESEARCH STUDY?

You will be reimbursed for your time, effort and travel while you are in this research study.

You will receive payment for this study in the form of a reloadable debit card (Clincard). We will give you a handout that will explain how to use the card. Because you are being paid for your participation, CCHMC is required by the Internal Revenue Service (IRS) to collect and use your social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay. You will need to complete a Federal W-9 form for this income tax reporting. This form requires your Social Security number. This form will be given to the CCHMC business office. It will not be kept as part of your study chart. If you move, you will need to complete another W-9 with an updated address.

You will be paid $500 for completing the study visits. The participation stipend will either be paid via Clincard Mastercard ® or submitted directly to your unit to disperse. The $500 compensation will be broken down as follows:
$150 for completing the initial study visits (MRI and EEG/Hearing)
$350 after completion of the training and follow-up visits (MRI and EEG/Hearing).

WHAT HAPPENS IF YOU ARE INJURED FROM BEING IN THIS STUDY?

This research does not require that the participant maintains participation in their job/training. The desire to participate in the training event is an independent, personal decision separate from the decision to enter into this study. During the course of this study, we expect that injuries consistent with the training will occur, such as head injuries, sprains, fractures, and muscle injuries. Some of these injuries may be severe and have severe consequences. *The choice to participate in the*

training and accept the risk of the participation in the training you have chosen is entirely a choice made by you. Neither the study investigator (Dr. Myer) nor CCHMC will be responsible for the medical treatment of any training related injuries. While the likelihood of an injury related to this research is small, if you believe that you have been injured as a result of this research you should contact Gregory Myer, PhD as soon as possible to discuss the concerns. Treatment for injuries is available at CCHMC. If you go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in a research study. If possible, you should give them a copy of this consent form.

CCHMC follows a policy of making all decisions about compensation for the medical treatment of physical injuries that happened during or were caused by research on an individual basis.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions, concerns, or complaints about this research study you can contact the study person listed on page 1 of this document.
If you would like to talk to someone that is not part of the research staff or if you have general questions about your research study rights or questions, concerns, or complaints about the research, you can call the CCHMC Institutional Review Board at 513-636-8039.

WHAT ELSE SHOULD YOU KNOW ABOUT THE RESEARCH?

If you are diagnosed with a concussion during participation in this study, your medical care will not be affected by your participation. While your insurance will not be billed for any testing associated with this study, any further care or treatment will be billed accordingly.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?
CCHMC will need to use and share your PHI as part of this study. This PHI will come from:
- Your CCHMC medical records
- Your research records

The types of information that will be used and shared from these records include:
- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

Who will share, receive and/or use your protected health information in this study?
- Staff at all the research study sites (including CCHMC)

- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the CCHMC Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your PHI is not misused?
People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?
You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?
Your permission will expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

Will your other medical care be impacted?
By signing this document you are agree to participate in this research study and give permission to CCHMC to use and share your PHI for the purpose of this research study. If you refuse to sign this document you will not be able to participate in the study. However, your rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you should participate in this research you will document your consent by signature below.

You will receive a copy of this signed document for your records.

_____
Printed Name of Research Participant

_____ _____

Signature of Research Participant Indicating Consent | Date

_____ _____

Signature of Legally Authorized Representative* | Date

_____

* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____ _____

Signature of Individual Obtaining Consent | Date