Evaluation of the Effectiveness and Safety of Transcorneal Electrical Stimulation To Improve Visual Function After Ocular Trauma

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Institution Receiving Award: WILLS EYE INSTITUTE
Program: DMRDP
Proposal Number: DM120101
Funding Mechanism: Clinical Trial Award - Regenerative Medicine, Pain, Sensory System
Partnering Awards:
Award Amount: $2,316,094.00

PUBLIC ABSTRACT

Has your car ever had a dead battery? How did you fix it? You might have replaced the battery with a new one or you might have "jump-started" your car by using an external battery and external cables. Think about how important electricity is to your car. It runs the starter to turn the motor on and powers all of the various electric components like the lights, turn signals, radio, and windshield wipers. It is an amazing invention and changed society as we know it. The human body is much like a car, essentially doing everything a car does and more - aren't your eyelids like windshield wipers? It is also an electrical marvel. Many of the organ systems of our body run on electricity. Perhaps the most well-known is the heart muscle. It has its own pacemaker to keep the muscle contracting at a defined rate, much like the engine keeping a car at a certain speed.

Another similar organ that runs on electricity is the eye. Just like a battery that has cells to store chemicals to produce current, the eye has specialized cells that enable you to see. These cells, the rods (black and white vision) and cones (color vision), store chemicals that change in response to light energy and turn it into electrical energy, which is transmitted along the retina to end up in the brain where the electrical impulses can be measured. We perceive this change in current as "seeing"! In some cases, the eye can have difficulty seeing either because of trauma to the eye or head or certain types of degenerations occurring in the eye.

In order to address these conditions of the eye, there are several potential approaches currently being evaluated. One is a transplant of the retina (putting in a new battery), which is complex and involves intraocular surgery and is still investigational. Another potential discovery, also investigational, is the use of an external electrode to "recharge" or "jump-start" the cells in the eye and follow the changes in the electrical current of the eye and vision. In this proposed research study, we will use the OkuStim device developed by OkuVision GMbH in Germany. The instrument will be placed on the cornea of the eye (outside of the eye) and deliver a predetermined electrical charge during a treatment. Hence, the name of this proposed treatment therapy is called Transcorneal Electrical Stimulation, or TES.

TES has already been used in several research studies including animals and humans with inherited degenerations of the retina. These studies have shown that by using TES, some of the cells in the retina involved in vision could be made to respond and that there was improvement in vision. Based on these preliminary results, we intend to determine if TES is useful in restoring vision (front and side vision) in persons who have had trauma to the eye. For these studies, we need 42 participants in each of the three groups.

All patients enrolled in the study will receive treatment. Subjects will be randomly assigned to either one 6-week session or two 6-week sessions. One-third of patients will receive SHAM treatment in addition to active treatment. SHAM treatment is where the TES device is placed on the eye, but electrical stimulation is not received. This allows us to compare the effects. You and the person evaluating the test...
results will not know if you received the stimulation or not. This makes comparisons of the results more accurate. During this entire time period, tests of vision will be performed. These tests include measuring your vision under various light conditions as well as the ability to see to the side. In addition, other tests to determine how well you can function following the treatment will be performed.

By participating in this research study, you may not only regain vision, but you may also be helping other people with greatly reduced vision. These studies are of interest to the military because of the increase in eye injuries during combat. The research study is associated with Department of Defense's priority areas including Vision Restoration and Vision Regeneration as well as Visual Rehabilitation Strategies.