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Phase I/II Multicenter Randomized Controlled Clinical Trial of Mesenchymal Stem Cell Therapy for Severe Ocular Surface Chemical Injuries

Principal Investigator: DJALILIAN, ALI
Institution Receiving Award: THE UNIVERSITY OF ILLINOIS AT CHICAGO
Program: VRP
Proposal Number: VR170180
Award Number: W81XWH-18-1-0661
Funding Mechanism: Clinical Trial Award
Partnering Awards:
Award Amount: $4,949,515.00

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PUBLIC ABSTRACT

Injuries to the eye represent a major cause of long-term suffering among Service members in combat. The most devastating injuries to the eye include severe thermal and chemical burns to the surface of the eye known as ocular burns. These burns often result from explosions, fires and/or exposure to chemical agents. While there are many therapies to relieve symptoms for ocular burns, we still lack any significant treatments that expedite the healing process, prevent scarring, and reduce loss of vision.

We propose a clinical trial involving at least 10 different clinical sites to test how quickly and to what extent a novel treatment can accelerate repair and prevent blindness. Clinical sites include two Veterans Administration medical centers and the Captain James A. Lovell Federal Health Care Center, the United States' first federal health care center that partners the Department of Veterans Affairs and the US Department of Defense (DoD) into a single, fully integrated federal health care facility. We will test this treatment after severe chemical/thermal injuries to the eye and in other wound healing diseases of the eye which are more common among older patients (including older US Veterans).

The proposed clinical trial involves a special type of cell known as mesenchymal stem cell. The cells for this trial, which come from a healthy bone marrow donor, will first be grown to high numbers in a special cell production facility (under Food and Drug Administration [FDA] guidance) then be shipped to the clinical sites. It will be applied to the surface of the injured/non-healing eye using a biological glue.

These cells have been shown to accelerate wound healing of the eye in previous DoD-funded laboratory research. Encouragingly, similar cells have been tested in patients outside the U.S. and found to have significant regenerative and anti-scarring effects without any notable risks.

Furthermore, these cells have been studied in patients in the United States (under FDA guidance) for other non-ocular conditions and found to be safe without any adverse effects. Therefore, the risks of this cell-based therapy are expected to be low and the rewards can be potentially high. The findings from our clinical trial will provide evidence to assess dosage, safety, and maximum efficacy of the stem cell treatment for ocular surface repair. The results of the trial will facilitate the process for obtaining approval from the FDA to make this treatment widely available for all patients. Thus, not only will these findings help the thousands of military personnel and Veterans, any patient with a non-healing eye surface will also have hope of returning to normal functioning.

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