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Research Article

A Clinical Study showing that Intravenous Infusion of an Exosome Solution is Safe and Effective for the Treatment of Neurodegenerative Disorders

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Abstract

Introduction: Neurodegenerative disorders (NDDs) are diseases, such as Amyotrophic Lateral Sclerosis (ALS) and Parkinson's Disease (PD), that affect the central nervous system. Currently, treatment options for these diseases consist of symptom management and mild delays in disease progression. Mesenchymal stem cell-derived exosome products (MSC-exos) are a notable area of interest in regenerative medicine due to their size, biocompatibility, and relative success in pre-clinical studies for the treatment of NDDs. We have previously demonstrated that intranasally administered MSC-exos are safe and effective for the treatment of NDDs, but there are currently no clinical reports regarding the safety and efficacy of intravenously administered MSC-exos. We hypothesized that intravenous infusion of MSC-exos would be completely safe and demonstrate efficacy for the treatment of NDDs.

Methods: After informed consent, we performed intravenous infusion of XoGlo Pro, a purified placental MSC-derived exosome product, in 16 patients with ALS, PD, or hearing loss. Patients also received two additional intranasal instillations of XoGlo Pro, Luxir+, Ascellos, or a combination of these products. Patients were evaluated immediately after treatment for signs of adverse events and improvements in disease-related symptoms.

Results: All patients reported that their treatment was painless with zero adverse events of any kind. 9 patients reported an immediate clinical improvement after the intravenous infusion of XoGlo Pro. One week after treatment, 5 patients who experienced immediate improvements remained better, while 2 patients who did not improve immediately also reported clinical improvements.

Conclusion: Intravenously infused MSC-exos, such as XoGlo Pro, are safe and demonstrate efficacy for the treatment of NDDs.

Keywords: Amyotrophic Lateral Sclerosis; Exosomes; Hearing Loss; Mesenchymal Stem Cell-Derived Exosomes; Neurodegenerative Disorders; Parkinson's Disease

Introduction

Neurodegenerative disorders (NDDs) are classified as diseases that slowly damage the nerve cells in the central nervous system (CNS) which, over time, will ultimately lead to a complete loss of neural function and death [1-3]. NDDs can affect the nervous system in a variety of ways including, but not limited to, demyelination, motor neuron dysfunction, neuroinflammation, and progressive brain damage, all of which result in an overall decline of cognitive function, coordination, and motor function [1,3]. Amyotrophic lateral sclerosis (ALS) and Parkinson's Disease (PD) are two of the most well-known NDDs with incidences of 1.75-3 and 8.6-19 per 100,000 people respectively [4,5]. Overall, it is estimated that around 57 million people worldwide suffer from NDDs, and that number is expected to double every 20 years [6]. There are no cures available. What currently exists are treatments that only aid in symptom management and mildly slowing down disease progression [3]. Due to the absence of treatment options for these diseases, and their severely debilitating nature, it is imperative that alternative treatment options be developed. Furthermore, pre-clinical trials using stem-cell-derived exosomes to treat ALS and PD in animal models have been performed showing some success [7,8], but with a lack of human data, it is clear that clinical trials must be performed to fill that void.

Exosomes are small vesicles, approximately 100-200 nm in diameter, that play key roles in cell-to-cell communication, tissue regeneration, inflammation modulation, immune regulation, and drug delivery [9]. Mesenchymal stem cell-derived exosome products (MSC-exos) require freezing but not liquid nitrogen preservation as MSCs do, thus making them easier to transport, store and use. For these reasons, treatment with MSC-exos is a prominent area of interest in regenerative medicine. XoGlo Pro (Kimera Labs, Inc., Miramar, Florida) is a purified placental MSC-derived exosome product that is designed for topical use but can potentially be administered systemically via intranasal (IN) or intravenous (IV) routes. A search of PubMed, however, discloses only one study, for COVID-19, where exosomes are used intravenously [10-12]. There are no clinical studies of IV exosomes for NDDs. We have previously demonstrated that IN exosomes can effectively treat NDDs in humans by bypassing the vascular blood-brain barrier. It would be very useful to determine if exosomes can similarly benefit NDDs with intravenous use. We hypothesized that their smaller size relative to MSCs may allow them to penetrate the tight junctions that largely prevent intravenous MSCs from being clinically useful for NDDs. We designed this study to

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show whether IV infusions of XoGlo Pro are safe for human use. As a secondary endpoint, we hypothesized that this treatment would show some efficacy for the treatment of NDDs.

Materials and Methods

All patients underwent baseline and post-treatment laboratory assessments, including Complete Blood Count (CBC), Complete Metabolic Panel (CMP), C-Reactive Protein (CRP), Interleukin-6 (IL-6), Tumor Necrosis Factor-alpha (TNF-a), Ferritin, and D-dimer. The post-treatment laboratory assessments were completed within 4 months following treatment.

After informed consent, 16 patients with Amyotrophic Lateral Sclerosis (ALS), Parkinson's Disease (PD), or Hearing Loss were treated over the course of 2 or 3 days. All 16 patients were treated by a licensed physician in the supine position with 5mL of XoGlo Pro infused intravenously and with two instillations of either 5mL of intranasal Luxir+ (Kimera Labs, Inc., Miramar, Florida), 9mL of intranasal Ascellos (Zizion Group, Boca Raton, Florida), 5mL of intranasal XoGlo Pro exosomes, or a combination of these products. The patients were observed for 15 minutes following each infusion. All patients were instructed to call after leaving the clinic if they experienced any adverse events. They were all followed up the next day either in person or by telephone as well as one week and one month after treatment by telephone.

12 of the patients were treated with intravenous XoGlo Pro on their first day of treatment. 2 patients received an intranasal instillation of 9mL of Ascellos exosomes on the same day as their intravenous infusion of XoGlo Pro. Therefore, only the clinical result within the first twenty-four hours of treatment for 10 patients was determined to be a reliable indicator of the isolated effect of the intravenous XoGlo Pro treatment. Of the remaining 4 patients that were treated with intravenous infusions of XoGlo Pro, 1 received the intravenous infusion on their second day of treatment and 3 received the intravenous infusion on their third day of treatment.

During their follow-up, patients were asked specifically about any improvements in their disease-related symptoms compared to their status before treatment. For ALS patients, these included bulbar, motor, and respiratory symptoms as well as muscle pain. For PD patients, the symptoms mostly presented as balance impairments, muscle stiffness and cramps, tremors, or as olfactory, gustatory, cognitive, gastrointestinal, and genitourinary impairments.

Results

No patients experienced any pain or adverse events during or after treatment. 9 of the 16 patients reported significant clinical improvement 24 hours after treatment. Having more energy and decreased stiffness were the most common benefits of the treatment, although some patients reported improvements in speech. One week after treatment, 7 patients stated that they had improved, including 2 patients that did notice any immediate response. There were no significant changes in the laboratory assessment results before and after treatment.

Discussion

This study demonstrates that intravenous infusion of XoGlo Pro is safe in human patients with NDDs and has clinical efficacy in a majority of such patients. No prior study has demonstrated efficacy of IV exosomes for neurocognitive disorders. It is the norm for the clinical effects of intra-nasal exosomes to manifest that evening. Hence, the responses on the night of treatment can confidently be ascribed to the XoGlo Pro treatment. However, since many patients in this study also had a different exosome or secretome treatment delivered intranasally, long-term improvement cannot be necessarily ascribed to intravenous XoGlo Pro alone. While combining treatments makes analyzing the efficacy more difficult, our top priority is to effectively treat our patients. Using multiple treatments was deemed to give patients the best chance to improve.

Regarding safety, the one prior published case series did not demonstrate serious adverse events. Our study mirrors that finding. The complete lack of adverse events validates our hypothesis that this treatment is safe, even when supplemented with intranasal MSC-exos.

Conclusion

Intravenously infused XoGlo Pro placental MSC-derived exosome product is completely safe and shows significant efficacy for neurodegenerative disorders.

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