Study Protocol

Analysis of the Safety and Efficacy of Administering Umbilical Cord Mesenchymal Stem Cell Secretome in Patients With Severe Erectile Dysfunction Non-responsive to Sildenafil

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Introduction and Objective

Couples who have difficulties in conception are estimated to be approximately 15 % of couples in the whole wide world, which is a significant challenge in reproductive medicine. Asthenoteratozoospermia is a critical factor in infertility in males due to the low motility of sperm and its structurally aberrant morphology. Because of the secretome that provides trophic factors, cytokines, and growth factors, mesenchymal stem cells (MSCs) have a significant therapeutic promise in regenerative medicine.(4) The secretome includes a range of bioactive molecules contributing to tissue remodeling, immune modulation, and angiogenesis. Bioactive molecules conveyed through a secretome regulate various phases of the cell. Therefore, the research aims to characterize the effects of Umbilical Cord-MSC (UC-MSC) secretomes on sperm quality in male asthenoteratozoospermia via measures of Reactive Oxygen Species (ROS) levels, anti-oxidant enzyme activity, and sperm parameters cell by transferring bioactive molecules.(6) Thus, the research goal is to investigate the impact of UC-MSC secretomes on sperm quality in male asthenoterazoospermia using indicators of ROS levels, activities of anti-oxidant enzymes, and sperm parameters.

This research evaluates the effects of UC-MSC-derived secretomes on sperm motility, concentration, and morphology. Secondary objectives involve determining ROS levels and anti-oxidant enzyme activity changes in sperm after exposure to secretomes, characterization of the molecular composition of UCMSC-derived secretomes, defining mechanisms of interaction with sperm cells, and understanding how UC-MSC-derived secretomes affect sperm function. The study hypothesizes that UC-MSC-derived secretomes will reduce ROS levels, enhance anti-oxidant enzyme activity, and improve sperm quality parameters in individuals with asthenoteratozoospermia.

MATERIALS AND METHODS

This study is an experimental study with a pre-post-test design. This design refers to a previous study by von Schwarz et al. which used stem cell injections in erectile dysfunction patients. This study was an experimental study with a pre-post-test research design with 12 subjects of severe ED non-responsive to sildenafil. The study involved men aged 40-65 years with severe erectile dysfunction unresponsive to sildenafil therapy, and samples were taken using a consecutive sampling technique.

The safety parameters measured included pain, hematoma, local bleeding, and infection. Efficacy parameters were measured through the IIEF-5 questionnaire, EHS, morning erection, SPL, FPL, penis circumference, and several ED evaluation examinations by PDCU. Color Doppler ultrasonography is an informative and minimally invasive tool useful in the diagnosis and evaluation of erectile dysfunction, especially in the evaluation of penile hemodynamics. Spectral Doppler analysis of the cavernosal arteries in the flaccid penis is a non-invasive method for assessing arterial disease and has been reported to have the best accuracy for predicting arterial insufficiency using a PSV cutoff value of 10cm/s in the cavernosal arteries.