

عنوان مقاله:

Preclinical Toxicity Study of Clinical Grade Allogeneic Human Bone Marrow-Derived Clonal Mesenchymal Stromal Cells

محل انتشار:

بیست و یکمین کنگره پزشکی تولید مثل و شانزدهمین کنگره زیست شناسی و فناوری سلول های بنیادی (سال: 1399)

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خلاصه مقاله:

Objective: Mesenchymal stromal cells (MSCs) have opened a new window for the treatment of inflammatory and non-inflammatory diseases. Nonetheless, its clinical applications require rigorous control and monitoring procedures to ensure compliance with all Good Manufacturing Practices (GMP) principles. For bench-to-bedside development of these newly-emerging therapeutic products, they should pass different stages from in vitro characterization to pre-clinical studies, in addition to clinical trial phases to ensure product safety and efficacy. In this regard, a robust pre-clinical study is critical to ensure product safety. The aim of this study was to determine the toxicity effects of local and systemic injection of human bone marrow-derived clonal mesenchymal stromal cells (hBM-cMSCs) in acute and sub-chronic periods. **Materials and Methods:** In the present study, hBM-cMSCs were characterized by defined criteria of ISCT for MSCs. The safety and toxicity of hBM-cMSCs population, produced in GMP compatible conditions, were assessed in both sexes of Sprague Dawley (SD) rats through systemic intravenous route and local injection in intervertebral disc (IVD). Changes in body weight, food and water consumption which are important variables in product toxicity tests were assessed. After passing the expected time periods (۱۴ days for the acute period and ۹۰ days for the subchronic period) and sacrificing the rats, laboratory tests and histopathology of target tissues were

performed on designated specimens. Also tumorigenicity was checked in nude mice. Results: Single injection of hBM-cMSCs through intravenous or IVD route during the ۱۴ and ۹۰-days period did not cause significant changes in clinical symptoms and laboratory data of all animals. Ex vivo-expanded and cryopreserved hBMCMSCs did not induce tumor formation in nude mice. Conclusion: The results suggest that local and systemic administration of allogeneic or xenogeneic hBM-cMSCs in both sexes of SD rats does not impose tumorigenicity and/ or toxicity in acute and subchronic periods.

کلمات کلیدی:

Toxicity, Bone Marrow Clonal Mesenchymal Stem Cells, Good Manufacturing Practices, Tumorigenicity

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