## THE SAFETY AND EFFICACY OF BONE – MARROW DERIVED CELL THERAPY IN CRITICAL LIMB ISCHEMIA, A STRUCTURED REVIEW

FARZANA BINTI MOHAMMED FAZALULLAH 100130430

MASTER OF SCIENCE (ANTI-AGING, REGENERATIVE MEDICINE AND MEDICAL AESTHETIC) FACULTY OF MEDICINE AND HEALTH SCIENCES, UCSI UNIVERSITY

## **ABSTRACT**

This study was aimed at assessing the safety and efficacy of bone marrow mononuclear cells and bone marrow derived tissue repair cells/tissue stem cells in the management of Critical limb Ischemia, especially due to the fact that there is a high incidence of mortality and morbidity in these patients without other options, except conventional medical management. This study provides a comprehensive structured review of literature about the safety and efficacy of bone-marrow derived cell therapy in Critical Limb Ischemia. A comprehensive search of PubMed, Cochrane Library, Medline and Google Scholar was conducted to identify the papers that study the benefits, efficacy and adverse effects that occurred in those patients with Critical Limb Ischemia receiving bone-marrow derived cell therapy. Out of 84 studies uncovered from the search, 15 studies were relevant, but only 6 studies met both inclusion and exclusion criteria. Among the trials sourced, all were comparative studies, which were either between bone marrow mononuclear cells and placebo/control or bone marrow mononuclear cells versus peripheral blood mononuclear cells. One trial was on bone marrow derived Tissue Repair Cells/Tissue Stem Cells versus placebo. Another trial used bone marrow mononuclear cells for both groups in the trial, but compared them with a blood cell separator and Ficoll density gradient centrifugation. Out of the selected studies chosen, significant improvements in ABI was observed with bone marrow mononuclear cell therapy in most of the trials. Similarly, statistically significant achievement of efficacy outcomes was seen in the majority of the patients who were treated with bone marrow mononuclear cells for ulcer healing, rest pain, pain-free walking time, transcutaneous O2 and prevention of major amputation. Generally, bone marrow mononuclear cell treatment was found to be safe and well-tolerated without the occurrence of major side effects due the treatment itself, but was clearly shown to be closely related to the severity of the disease itself and its associated co-morbidities.