

Proposed Clinical Trial to Evaluate the Role of Umbilical Cord Blood derived Mesenchymal Stem Cell in Managing Postoperative Pain and reducing the Use of Opioid Pain Medication

Background

Since the early 2000s the rates of opioid overdose have tripled and now rank as the leading cause of death related to unintentional injury ^{6,7}. The President of the United States Commission on the Opioid Crisis published the death rate to be over 300,000 Americans ². Prescription drugs are implicated in most of the cases, as rates of opioid prescriptions quadrupled ^{8,9} and were paralleled by increasing rates of deaths from overdose. Non-fatal overdose events from prescription opioids account for 7-11 times more episodes than fatal overdoses ^{10,11} and have similarly increased by more than 50% over 10 years.¹¹ Strikingly the majority of these non-fatal overdose episodes take place in patients identified as non-chronic (<90 days) opioid users

Making opioids the focus of pain management has created many unintended consequences that often put both patients and their families at increased risk of addiction and death. Therefore, it is widely recommended that a new approach to pain management is needed to effectively change the cultural expectations of patients with pain ¹. Patients with similar injuries and surgeries experience varying amounts of pain. The differences in pain for a given injury or surgery are largely explained by individual patient circumstances, characteristics, and mindset. Stress, distress, and ineffective coping strategies create greater pain. Peace of mind is the strongest pain reliever. Studies have found that opioids are associated with more pain and lower satisfaction with pain relief. Opioids are potentially dangerous medications for all patients; they are highly addictive and can cause death.

In the United States, the current cultural expectation of opioid use as the primary treatment for acute and chronic pain has created an opioid epidemic. Only a culture change led by physicians dedicated to limiting inappropriate opioid use will solve this epidemic. Physicians, patients, and caregivers in the United States need to learn how to treat pain with less dependency on opioid medications ³.

According to a recent study, “each refill and week of opioid prescription following surgery is associated with an increasing risk of opioid misuse among opioid naïve patients” ⁵.

Recent clinical practice and expansion in the use of Mesenchymal Stem Cell Allograft have demonstrated promising results. Patients injected with stem cells allograft at conclusion of surgical intervention in common orthopedic procedures such as shoulder arthroscopic rotator cuff and labral repairs, knee arthroscopy and ACL reconstructions have shown a decrease in use

of narcotic pain medication in the postop recovery period. Patient self-reporting demonstrates dramatic decrease in use of narcotic medication and that the majority of patients treated with stem cell allograft versus none. Use of stem cell allograft required the informed consent of the patient, an extensive medical counselling by the physician and medical staff, and the use of non-narcotic medication alternatives is postulated as adequately educating the patient, bringing peace of mind and decreased fear of pain, and patient understanding of stem cells, all contribute to the diminution of narcotic use. Individual case studies demonstrated that the majority of patients use a total of 1 to 7 narcotic pain pills in the postop period. Patients undergoing equivalent surgery without stem cell allograft injections use between 40-60 narcotic pain pills in the postop period. The clinical demonstration of beneficial results in 25 patients is sufficient evidence of proof of concept warranting further investigation.

The purpose of this study is to determine the appropriateness of clinical stem cell therapy for the heterogeneous orthopedic surgical patient population routinely seen in practice. The best available scientific evidence is synthesized and developed into this clinical protocol for appropriate management of postoperative pain and acceleration of healing. We propose that when there is evidence corroborated by consensus that expected benefits substantially outweigh potential risks exclusive of cost, a procedure is determined to be appropriate.

Aligned with the American Academy of Orthopedic Surgeons (AAOS), the authors' philosophy is that evidence-based medicine is an integral component of treatment decisions and that the best results are predicated on reciprocal communication between the patient and physician and an individualized regimen where risks are minimized, and benefits are maximized. Medical expertise that is informed by research and takes into account that the possible options increases the likelihood that patients' symptoms will be managed effectively.

Materials and Methods

Outcomes Measures

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