Clinical Trial Number: NCT04731233

Title: A Randomized, Double-Blind Study of the Efficacy of Platelet-Rich Growth Factor (PRGF) Supplementation Compared to Steroid Supplementation After Temporomandibular Joint (TMJ) Arthrocentesis in Female Patients With TMJ Osteoarthritis (OA)

Date: January 2, 2025

Protocol

Protocol:
Temporomandibular disorders (TMD) are musculoskeletal disorders that are commonly encountered, with pain in the temporomandibular joint (TMJ) and jaw closing muscles. Pain that involves the temporomandibular joint includes inflammatory pathologies such as arthritis, painful disk displacements and many times have an overlay of psychosocial comorbidities due to the uncontrolled pain. TMJ osteoarthritis is an intracapsular condition affecting the temporomandibular joint and presents with remodeling of the TMJ articulating tissues including the condyle and articular eminence secondary to inflammation resulting in intracapsular pain. There is a paucity of information regarding the relative effectiveness of different therapies for the treatment of patients with TMJ osteoarthritis. The identification of the least invasive and most efficacious therapy is vital to proper management of these patients with temporomandibular joint pain and disability. The purpose of this study is to establish the relative efficacy of TMJ arthrocentesis with steroid supplementation (a known effective therapy) compared to TMJ arthrocentesis with a supplement of plasma rich in growth factors (PRGF) for patients with TMJ osteoarthritis. Plasma rich in growth factors is isolated from the patient's own blood and injected into the temporomandibular joint to activate stem cells that may restore some of the articulating tissues that were lost during degeneration changes within the joint secondary to osteoarthritis. Pain and disability will be assessed using standard pain and physical measures that are recorded before and after treatment. Patients enrolled into the study will be examined and treated at the Department of Oral and Maxillofacial Surgery Faculty/Resident clinic. At the first appointment, they will be examined following standard procedures (medical history, physical exam, imaging by cone beam computerized tomography (CBCT)) to determine their diagnosis(es) and if they would potentially benefit from the TMJ arthrocentesis procedure. If the patient meets the inclusion criteria for the study and with their informed consent on the day of their TMJ arthrocentesis procedure, they will be required to have a pregnancy test if below age 60 and complete a questionnaire about their physical and pain symptoms and undergo a standardized clinical exam. The patients will then undergo the standard clinical protocol for TMJ arthrocentesis followed by either a 2 cc steroid/bupivacaine hydrochloride supplementation (standard treatment group) or a 2 cc PRGF supplementation (experimental group) into the TMJ. Follow-up appointments will be conducted at 1 month, 3 months and 6 months when the pain VAS measures and a clinical exam will be assessed. If patients have not experienced improvement in their primary outcome measure (TMJ pain) at the 3 month evaluation, the patient will have a second TMJ arthrocentesis procedure that will be supplemented with the alternative medication/growth factors (steroid or PRGF) using a cross-over design. Data from these patients will be analyzed separately from patients that complete the six month study. Also at 6 months, a second CBCT image of the temporomandibular joints will be obtained to determine the extent of bone remodeling within the TMJ. The results of this study should provide new information on the efficacy of PRGF supplementation for management of temporomandibular joint osteoarthritis.