ABSTRACT

Background: Temporomandibular joint (TMJ) pain, known as TMJ arthralgia, is caused by inflammation in the TMJ. Treatment often involves non-steroidal anti-inflammatory (NSAIDs) pills, which act against inflammation and pain. The side effects with long-term NSAID pill limit how long they can be used, even in patients with chronic TMJ pain. For this reason, a cream formulation of an NSAID has been used for TMJ pain, with results similar to the NSAID pill. Corticosteroids are stronger anti-inflammatory agents than NSAIDs. For TMJ pain, they are delivered as pills or as injections into the TMJ. However, the side effects of the pills, and the skill required for injection into the TMJ, limit the use of these delivery modes. Topical steroids have never been investigated as a treatment for joint pain, though their efficacy (compared to topical NSAIDs) and safety (compared to corticosteroid pills or injections) are promising. **Study Design:** This will be a double-blind, randomized clinical trial. Patients of the dental school who are diagnosed with TMJ arthralgia will be invited to participate. Sample size calculations using 0.05 alpha and 0.9 power, deeming 30% pain reduction as clinically significant, and allowing for a 20% drop-out rate, determined a necessary sample size of 90 participants (45 per group). For blinding of subjects and the provider, cream tubes will appear identical, differing only by their identification number (will be generated with a random number generator), with a confidential key linking the tube number and content; this key will only be access after data analysis is complete. For random allocation, the order in which tubes will be dispensed (one per subject) will be determined by a list randomizer. Subjects apply the cream 4 times daily to the TMJ, and will complete pain questionnaires on Day 0 and Day 21.