



AMERICAN ACADEMY OF FAMILY PHYSICIANS FOUNDATION

Abstract of Study Funded by the Joint Grant Awards Program in 2008

The Efficacy of Prolotherapy for Lateral Epicondylitis: a pilot study (G0810)

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Abstract

Abstract Background: Chronic lateral epicondylitis (CLE, “tennis elbow”) is a common, debilitating and expensive condition accounting for 4-7/1000 primary care office visits annually and has a prevalence of up to 30% among industrial workers. No uniformly effective therapy is currently available for this chronic disorder. Prolotherapy (PrT) is an injection-based technique with a 100-year history suggesting effectiveness for musculoskeletal pain. It has not been well studied as a treatment for tendinopathy. **Goal:** The primary goal of this AAFP/F grant application is to conduct a pilot study to assess the efficacy of PrT as a pain-control and disease-modifying treatment modality for CLE.

Preliminary studies: The PI has recently collaborated on a clinical trial of PrT for CLE that yielded very promising results. Subjects receiving PrT, compared to those in a saline injection control group, showed dramatically reduced pain and function improvement on non-validated outcome measures. The proposed study will build on the success of this prior trial by using a validated, disease-specific clinical outcome measure as the primary outcome, and by adding biomechanical and radiological secondary outcome measures. **Methods:** The PI will conduct a pilot RCT of PrT. **Thirty adult subjects with refractory CLE** will be randomly assigned to one of three groups: PrT using dextrose and sodium morrhuate (Group 1), PrT using dextrose alone (Group2), or a waitlist control group (Group 3). A sham injection control group was not chosen because the results of a prior study showing no effect of sham saline injections. Groups 1 and 2 will receive PrT injections at 0, 4, 8, 12 weeks. Assessment will be with clinical, biomechanical and radiological measures through 16 weeks. The primary outcome measure will be a score on the validated, disease-specific Patient-Rated Tennis Elbow Evaluation. Secondary measures include five objective mechanical measures (pain-free and maximum grip strength, stiffness, effective mass and damping) as well as pre- and post-treatment appearance of lateral elbow structures on ultrasound and magnetic resonance imaging. Waitlist subjects will be offered PrT at 16 weeks because 1) prior data suggests a plateau of PrT’s clinical effects at 16 weeks and 2) we doubt that subjects with severe elbow pain will remain in the Waitlist group past 16 weeks. They will be followed in a case series separate from this application. Groups 1 and 2 will be assessed through 32 weeks. We will assess adverse events and subject expectation with serial questionnaires and patient satisfaction using a qualitative exit interview. **Significance:** The proposed RCT will be the first to use methodologically rigorous outcome measures in a study of an injection therapy, PrT, for CLE, a major tendon disorder. Positive results would suggest the effect size of PrT for CLE, informing the calculation of a sample size to power a larger study; they would also suggest the need for assessment of PrT for other tendinopathies. Statistically positive results on clinical, biomechanical and radiological outcomes would suggest that prolotherapy decreases pain and disability, modifies the disease, and may even be a cure for CLE, providing enormous benefits to patients, industry and society.