Flare Study Protocol

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1. Purpose

Triamcinolone acetate (TA) and methylprednisolone acetate (MA) are standard of care (SOC) medications administered in shoulder injections depending upon Physician preference. The Physicians involved in the study have observed a difference in the rate of call backs following shoulder injection due to a reported increase in shoulder pain following the SOC injection. The purpose of this study is to compare the incidence of a flare reaction following administration of TA versus MA intra-articular glenohumeral and subacromial injections.

For the study, a flare reaction is defined as an increase of 2 or more from the baseline score on the visual analog score (VAS) in the first week following the shoulder injection.

2. Patient Enrollment

The study is a non-randomized, prospective, parallel-cohort study among subjects treated according to standard of care. Subjects will be approached for participation after electing to receive a corticosteroid injection in the glenohumeral joint or subacromial space as part of their SOC treatment plan. Three months was allotted for enrollment into the MA cohort followed by three months of enrollment into the TA cohort.

3. Inclusion Criteria

Any patient aged 18 to 95 who pursues a corticosteroid injection in the glenohumeral joint or subacromial space from one of three primary orthopedic Sports medicine or Shoulder specialists.

4. Exclusion Criteria

Patients will be excluded if they have received a corticosteroid injection in the previous three months.

5. **Outcome Measures**

The primary outcome measure is the incidence of a Flare reaction.

Secondary measures include VAS scores collected at the three-month time point. Another secondary measure is "treatment failure," defined as a VAS score equal to or greater than a subject's baseline VAS score. Subjects that proceed to another injection or surgery will also be defined as "treatment failures."

6. **Study Procedures**

The consent form will be utilized to explain the study design to prospective subjects in a private room. Adequate time will be allotted for questions and answers with the study team. The pre-injection VAS will be administered in clinic. VAS scores for the week following injection will be obtained through a "home diary" data collection tool labeled with a subject code. After completing the "home diary" tool, patients will mail the stamped, form to the study administrator. The three-, six-, and twelve-month VAS scores will be collected by phone interviews with research staff.

7. **Statistical Analysis Plan**

Data will be collected and summarized by research staff. Advanced statistical analysis will be performed, including risk ratios for flare reaction development by cohort as well as standard and adjusted regression models.

8. **Risk to Subjects**

Subjects may experience tiresome or troublesome feelings while completing VAS scores through the "home diary" or phone interviews with research staff. Loss of confidentiality is a potential risk disclosed to subjects.

9. **Benefit to Subjects**

There are no direct benefits to subjects outside of the possible benefits of the SOC procedures being studied. However, the findings from the study may contribute to generalizable knowledge as assist with decision making practices at Campbell Clinic.

10. **Subject Discontinuation**

Subjects will not be contacted for subsequent study procedures if the subject withdraws from the study or if they are determined to have "failed" treatment.

11. **Adverse Events**

No incidental adverse advents are expected as all study procedures are currently SOC.

12. **Data Handling, Collection, and Record Keeping**

Baseline VAS scores will be collected in clinic prior to injection. “Home diaries” will be mailed by subjects to research personnel in a manner that protects study confidentiality. Three-month VAS scores will be obtained through phone interviews conducted by research personnel. All data will be combined into a secure, password-protected electronic data capture (EDC) tool.