BIOMEDICAL RESEARCH PROTOCOL
UNIVERSITY OF MISSOURI

Project Title: Differential Efficacy of Corticosteroid Solutions for Non-Operative Treatment of Digit Flexor Tenosynovitis: A Double-Blind Prospective Randomized Clinical trial.

IRB Number: 2014039
Version Number: 2.0
Version Date: 27 JUL 2020
Principal Investigator: Dr. Sebastian Lalonde

Background:

Idiopathic stenosing tenosynovitis of the digits, more commonly known as trigger finger, is a common cause of hand pain and dysfunction. Many previous studies have described the pathophysiology of this condition and it can be summarized as inflammation of the flexor tendons leading to a size mismatch between the tendon and the flexor pulley system. By far the most common location of this mismatch is at the A1 pulley.

The current mainstay of treatment has been:

1. Injection of corticosteroid into the area immediately surrounding the A1 pulley and flexor tendon
2. Surgical release of the A1 pulley

Several corticosteroids have been used for injection- dexamethasone, methylprednisolone, triamcinolone, betamethasone, paramethasone, etc. Less commonly used treatment strategies have included: topical NSAIDs and extracorporeal shock therapy. The typical progression of treatment is one or two steroid injections and then surgical release if injections have failed.

To our knowledge, there have been no head to head comparison studies of the efficacy of different corticosteroid formulations in preventing conversion to surgical treatment. In our study, we will look at the efficacy of two of the most commonly used steroids: triamcinolone and dexamethasone.

Objectives:

Primary outcome: Treatment success, defined as lack of conversion to surgical treatment, or no desire to proceed with surgery during study period (3 months).

Secondary outcomes: Grade of triggering (Green classification of trigger finger severity[1]), QuickDASH and PROMIS Upper Extremity scores, VAS.

Study Question/Hypothesis:

We hypothesize that a 0.5 cc injection of Triamcinolone 40 mg/mL will be the most effective steroid injection for the non-surgical treatment of trigger finger.

Inclusion/Exclusion:

Inclusion criteria:

1. Adults aged 18 years and older
2. At least one symptomatic trigger finger
3. Patients recommended to receive corticosteroid injections

Exclusion criteria:

1. Previous surgeries/injections for trigger fingers in digit being treated for study
2. Participating in another clinical trial
3. Inability to receive corticosteroid injections (i.e. allergies, adverse reactions, etc.)
4. Unable to sign informed consent
5. Pregnant or plan to become pregnant

Number of Subjects:

Approximately 200 subjects will be enrolled.

Study Procedures/Methods:

Enrollment/Randomization/Treatment Visit:
Eligible patients presenting with primary flexor tenosynovitis will be enrolled on a voluntary basis. Prior to the injection, subjects will have already completed the PROMIS and QuickDASH surveys as part of standard care.

Enrolled patients will be randomized to one of three treatment arms:

1. Triamcinolone 40mg/mL
2. Triamcinolone 10mg/mL
3. Soluble dexamethasone 4mg/mL

Each study patient will receive the appropriate corticosteroid injection in the affected digit(s), consisting of a 1:1 mixture of 1% lidocaine plain and corticosteroid, total volume 1cc.

Blinding:
Syringes will be prepared and masked with opaque tape by the clinic nurses, thus providing blinding for providers administering the injection.

Follow-Up/Clinic Visits:
Subjects will be re-evaluated at 6 weeks post-injection and, if still symptomatic, will undergo a second injection of the same corticosteroid solution. At final follow-up (12 weeks), symptomatic patients who have failed treatment after 2 injections will be offered surgical release of the A1 pulley. Subjects who refuse a second injection at 6 weeks follow-up will be offered surgery, and the reason for refusal (treatment failure) will be recorded.

The visits and all research activity will be outlined below:

6 Week Follow-Up:

- Objective Measures:
    - Grade of triggering (Green classification of trigger finger severity1)

- Subjective Measures:
    - QuickDASH
    - PROMIS scores
    - VAS
- Second Corticosteroid injection (if subject still symptomatic)

12 Week (3 Month) Follow-Up (if applicable):

- Objective Measures:
    - Grade of triggering (Green classification of trigger finger severity1)
- Subjective Measures:
    - QuickDASH
    - PROMIS scores
    - VAS

6 Month Follow-Up:

The patient will be contacted via a phone call or Patient IQ to check on the status of their condition. If they are still experiencing a degree of triggering they will be advised by their physician to return to clinic for a standard of care visit. If they are no longer experiencing triggering, they will be asked to complete a survey over the phone or through Patient IQ only.

Specimen Collection: If a patient is recommended to undergo surgery at the end of the study, the tendon and capsule that is normally resected and discarded after surgery will be collected for analysis. After collection these tissues and data will be identified from the patient and assigned a number for use in study analysis. **We seek to only collect tissues from patients that are normally removed and discarded during trigger finger release procedures. None of the patients will undergo additional surgical procedures for the collection of tissues in this study.** For simplification purposes, potential subjects must agree to the collection of these specimens to participate in the study, even if they do not end up needing surgical intervention.

The collected tissue will be formalin-fixed and processed for histological sectioning for routine and immunohistochemical staining to assess and score degree of tissue pathology and effects of injections on treated tissue in order to effectively test the hypothesis.

Potential Risks:

There could be risk of accidental data breach/breach of confidentiality, and this will be minimized by having patient collected de-identified data locked separate from the decoder list linking subject number to patient MRN.

Potential Benefits:

Potential benefits include relief of their trigger finger pain and function. Steroid injections have been shown to provide symptom relief for patients suffering from trigger finger. We also hope to demonstrate a differential efficacy between different corticosteroid formulations, which would help guide future clinical decision-making.

Compensation:

The subjects will not be compensated for their participation in the study.

Costs:

The subjects will be financially responsible for all of their standard of care treatment and the corticosteroid injections are considered standard of care and will be billed to their insurance.

Statistics/Power:

We define a clinically significant difference in treatment efficacy as an absolute risk reduction of surgery of 20% (NNT = 5) between steroid formulations.

Based on our power calculation, 158 patients are required to have a 90% chance of detecting, as significant at the 5% level, an increase in treatment success of corticosteroid from 70% in the control group to 90% in the experimental group.

We plan to enroll 200 subjects to account for subjects that do not complete the study or are lost to follow-up.

References:

1. Wolfe SW, Hotchkiss RN, Pederson WC, Kozin SH, Tendinopathy, in: Green's Operative Hand Surgery, 6th edition, Churchill Livingstone, Chap. 62, p. 5, 2011.