Protocol:

Investigating Differences in Flare Reaction Incidence and Intensity Following Trigger Finger Injections Using Betamethasone and Methylprednisolone

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Protocol Number & Study Protocol Title

2103263450: Investigating Differences in Flare Reaction Incidence and Intensity Following Trigger Finger Injections Using Betamethasone and Methylprednisolone

Abbreviations List

VAS: Visual Analog Scale

Section I: Team and Research Summary

Study Team Composition

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Research Summary

Study Population –
80-100 patients to be recruited.
Inclusion Criteria:
Adult
Single trigger injection
First time for the digit
No prior surgery on digit
Exclusion Criteria:
Current oral steroid use
Rheumatoid arthritis
More than one single digit involved
Previous injection in same digit
Prior surgery on same digit
Other injections in the same clinic on the same day

Study Design – The two standard of care corticosteroids used for trigger finger treatment are betamethasone and methylprednisolone. Both injections are effective in treating trigger finger and the decision of which to use in treatment is currently a matter of the current practice and physician preference. There is no literature comparing the side effects, specifically flare reactions between these two treatments. Our goal through this randomized trial is to see whether there is a difference between these two corticosteroids in inducing flare reactions and if there are any differences in the peak level of pain and its duration. We will carry out a double-blinded randomized trial enrolling patients into one of the two treatment groups. The volume of the doses of steroid to be given will be standardized to 1 cc of either methylprednisolone (40 mg) or betamethasone (6 mg). We will instruct patients who meet the inclusion criteria to complete a visual analog scale (VAS) of their pain (1-10) prior to the injection, immediately after the injection, five minutes after the injection, and once a day for a minimum of 7 days after the injection. The incidence, intensity, time to peak and time to resolution of the flare reactions (defined as a 2-point increase from pre-injection pain) will be assessed and compared between the two groups. Findings indicating a statistically significant difference in the incidence and/or intensity of the flare reactions would be clinically significant and would be evidence supporting the switch of current standard practice to one corticosteroid over the other. Patients will only receive a single, standard of care, trigger finger injection on the day they present to the clinic. The next 7 days, up to two weeks if needed, of follow-up will only be a single short survey question to determine pain level.
Patients will be identified by the surgeon on the day they present to clinic, and will be recruited and consented by the study personnel. Data will be collected from the patient and stored in the REDCap server. There is not more than minimal risk involved.

Study Duration –
Enrollment: could take up to a year, depending on how long it takes to recruit enough patients.
Data Collection: 3-6 months after conclusion of patient enrollment
Analysis: 3-6 months after conclusion of data collection

Section II: Design

Background & Significance

Corticosteroid injections are effective non-surgical approach to treating trigger finger (stenosing tenosynovitis) with success rates reported as high as 92% after just one injection [1]. Among their side effects is a post-injection flare of increased pain that is attributed to crystal-induced synovitis [2]. Reports of these flares in the literature have been rare. Recent evidence their incidence can be as high as 33% [3]. We feel they are a more common clinical issue than traditionally reported and it would be beneficial to control and reduce their incidence if possible.

Two common corticosteroids used for trigger finger treatment are betamethasone and methylprednisolone [4][5]. Both injections are effective in treating trigger finger and the decision of which to use in treatment is currently a matter of the current practice and physician preference. There is no literature comparing the side effects, specifically flare reactions between these two treatments. Our goal through this randomized trial is to see whether there is a difference between

these two corticosteroids in inducing flare reactions and if there are any differences in the peak level of pain and their duration.

We will carry out a double-blinded randomized trial enrolling patients into one of the two treatment groups. The volume of the doses will be standardized to 1 cc of either methylprednisolone (40 mg) or betamethasone (6 mg). We will instruct patients who meet the inclusion criteria to complete a visual analog scale (VAS) of their pain (1-10) prior to the injection, during the injection and once a day for the following 7 days after the injection. We estimate that we need a minimum of 30 patients in each group to achieve a minimum of 80% power and 0.05 significance. The incidence, intensity, time to peak and time to resolution of the flare reactions (defined as a 2-point increase from pre-injection pain [3]) will be assessed and compared between the two groups. Findings indicating a statistically significant difference in the incidence and/or intensity of the flare reactions would be clinically significant and would be evidence supporting the switch of current practice to one corticosteroid over the other.

REFERENCES: See References section

Objectives

Two common corticosteroids used for trigger finger treatment are betamethasone and methylprednisolone. Both injections are effective in treating trigger finger and the decision of which to use in treatment is currently a matter of the current practice and physician preference. There is no literature comparing the side effects, specifically flare reactions between these two treatments. Our goal through this randomized trial is to see whether there is a difference between these two corticosteroids in inducing flare reactions and if there are any differences in the peak level of pain and their duration.
Findings indicating a statistically significant difference in the incidence and/or intensity of the flare reactions would be clinically significant and would be evidence supporting the switch of current practice to one corticosteroid over the other.

Study Design & Methodology

The two standard of care corticosteroids used for trigger finger treatment are betamethasone and methylprednisolone. Both injections are effective in treating trigger finger and the decision of which to use in treatment is currently a matter of the current practice and physician preference. There is no literature comparing the side effects, specifically flare reactions between these two treatments. Our goal through this randomized trial is to see whether there is a difference between these two corticosteroids in inducing flare reactions and if there are any differences in the peak level of pain and its duration. We will carry out a double-blinded randomized trial enrolling patients into one of the two treatment groups. The volume of the doses of steroid to be given will be standardized to 1 cc of either methylprednisolone (40 mg) or betamethasone (6 mg). We will instruct patients who meet the inclusion criteria to complete a visual analog scale (VAS) of their pain (1-10) prior to the injection, immediately after the injection, five minutes after the injection, and once a day for a minimum of 7 days after the injection. The incidence, intensity, time to peak and time to resolution of the flare

reactions (defined as a 2-point increase from pre-injection pain) will be assessed and compared between the two groups. Findings indicating a statistically significant difference in the incidence and/or intensity of the flare reactions would be clinically significant and would be evidence supporting the switch of current standard practice to one corticosteroid over the other. Patients will only receive a single, standard of care, trigger finger injection on the day they present to the clinic. The next 7 days, up to two weeks if needed, of follow-up will only be a single short survey question to determine pain level.
All survey data will be collected from the patient in real-time, but the study will include a retrospective chart review to collect demographic information, injection specifics, etc.
Data to be collected: information from your existing medical records, and new information about you that is created or collected during this study, such as: history and physical information pertaining to trigger finger, nursing and staff notes pertaining to trigger finger, identifiers (name, MRN), demographic data (age/date of birth, sex, dominant hand), patient reported outcome measures scores, comorbidities (tobacco use, diabetes, fibromyalgia).
This study does not involve more than minimal risk. Risks from participation in this study include typical risks associated with a trigger finger injection: pain at injection site, soreness, etc.
The subject will receive no direct benefits. Knowledge gained from this study could help change standard of care procedures for trigger finger injections to best limit flare reactions afterward.

Target Population & Recruitment Methods

We will recruit a minimum of 30-40 patients into each treatment group. Power analysis shows that at least 30 patients are needed to show a difference of 2-point difference between the two groups which corresponds to the minimal clinically important difference on the VAS scale assuming a standard deviation of 2.5 points. Accounting for the potential of patient data loss during follow-up surveys, we expect to need to consent and enroll 80-100 patients

Inclusion & Exclusion Criteria –
Inclusion: Adult, Single trigger injection, First time for the digit to be injected, No prior surgery on digit
Exclusion: Current oral steroid use, Rheumatoid arthritis, More than one single digit involved, Previous injection in same digit, Prior surgery on same digit, Other injections in the same clinic on the same day, Under 18, Cognitively impaired individuals, Pregnant women, Prisoners, WVU/WHUH/UHA Employees or students

Recruitment –
Prospective subjects will be identified by the surgeon at the time of their appointment. The surgeon will inform the study coordinator of a potential participant, and the study coordinator will approach the patient for consent.
There will be n flyers or other advertisements.

Risk & Benefit

Risk – Risks from participation in this study include typical risks associated with a trigger finger injection: pain at injection site, soreness, etc.

Benefit – The subject will receive no direct benefits. Knowledge gained from this study could help change standard of care procedures for trigger finger injections to best limit flare reactions afterward.

Statistical Analysis Plan

Power analysis showed that a minimum of 30 patients are needed to show a difference of 2-point difference between the two groups which corresponds to the minimal clinically important difference on the VAS scale assuming a standard deviation of 2.5 points. We will compare the incidence, intensity, and time to flare reactions and time to resolution between the two groups using t-test and chi square tests as appropriate.

Data Safety Monitoring – Yes, there is a data safety monitoring plan in place for this study.

Safety Monitoring & Unanticipated Event Reporting

Adverse events will be evaluated regarding their relevance and significance to the study. Unanticipated adverse events will be reported to the IRB if the AE is unexpected, serious, and has implications for the conduct of the study. The relationship of the unanticipated, serious adverse event to research participation will be determined by the PI. The PI will report promptly to the IRB any adverse events that are unanticipated and involve direct harm to subjects and any unanticipated events that involve risk but not direct harm to the subject according the ORIC SOPs.
An SAE that is study related, unexpected, fatal or life-threatening will be reported to the IRB as soon as possible but no later than 5 calendar days of becoming aware of the event. An SAE that is unexpected but not fatal or life-threatening will be reported to the IRB as soon as possible but no later than 10 calendar days after first knowledge. The clinical research coordinator will be monitoring and collecting all adverse events.

Study Duration & Timeline

Enrollment: could take up to a year, depending on how long it takes to recruit enough patients.
Data Collection: 3-6 months after conclusion of patient enrollment
Analysis: 3-6 months after conclusion of data collection
Approximate end date: Two years after IRB approval.

Section III: Informed Consent Process

Protected Health Information (PHI)

Identify whether your research will deal with protected health information (PHI). PHI is any information in the medical record or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service such as diagnosis or treatment. PHI: This is not limited to only retrospective studies and chart reviews; prospective surveys may also be contain questions regarding PHI.

1. Names

2. All elements of dates (except year) – this includes dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and

elements may be aggregated into a single category of age 90 or older

3. Phone number(s)
4. Electronic mail (E-mail) addresses
5. Medical Record numbers
6. Sex
7. Dominant Hand
8. Patient Reported Outcome Measures Scores
9. Comorbidities: Tobacco Use, Diabetes, Fibromyalgia
10. Related to trigger finger: history and physical information, nursing and other staff notes

Informed Consent Process

Prospective subjects will be identified by the surgeon at the time of their appointment. The surgeon will inform the study coordinator of a potential participant, and the study coordinator will approach the patient for consent. Consent will occur at the WVU Medicine UTC Orthopaedic clinic, in the patient's room, at the time of the patient's appointment. Patients will be given a copy of the study informed consent form to review before signing, as well as having the study coordinator go over it with them. They will be able to ask questions at any time during the process.

Confidentiality & Privacy

Confidentiality –
The data will be stored in the study REDCap, maintained by the WVCTSI. Identifiers will be stored in a separate location from the record ID and only study team members will have access to the information. Data will be destroyed 3 years after study closure. All study activity, such as medical record reviews, patient phone calls for survey responses, ets will be conducted in a private location where incidental viewing could not occur. Any physical copies of patient data collected will be stored in a locked desk drawer or fila cabinet at the University Town Center clinic.

Section IV: Other Considerations

Conflict of Interest

No conflicts of interest

Publications, Presentations, & References

To be determined

References

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5. Cecen GS, Gulabi D, Saglam F, Tanju NU, Bekler HI. Corticosteroid injection for trigger finger: blinded or ultrasound-guided injection? Arch Orthop Trauma Surg. 2015 Jan;135(1):125-31. doi: 10.1007/s00402-014-2110-9. Epub 2014 Nov 9. PMID: 25381472.