Consent

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

NCT04900220

August 8, 2022

Key Information for:

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

You are being asked to participate in the research described below. This page provides key information that may help you to make this decision; more detailed information can be found after this section.

Why is this research being done and what is involved?

- The purpose of this study is to determine whether one of two current standard of care corticosteroid injections for trigger finger is more beneficial for the patient than the other.
- You will be asked to answer a single survey question at multiple time-points: before the injection, immediately afterward, five minutes after the injection, and once daily for the following week.
- Your study participation will conclude after you answer the short questionnaire, no later than day 14 post-injection.

Do I have to participate and what are the risks involved?

Participation in this research study is completely voluntary and you are free to withdraw from the research at any time. If you do not wish to participate, please discuss alternatives with the study doctor or refer to the "Alternatives" section in the consent form. You may or may not directly benefit from participating in this research.

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

Who can I talk to if I have questions or concerns?

If you have any questions or concerns about this research or would want to withdraw from the study, you can contact Jenn Eicher at jeicher@hsc.wvu.edu or 304-285-7445, Research Coordinator in the Dept. of Orthopaedics, Hand Service at West Virginia University.

For more information, please see the Informed Consent Form.

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Informed Consent for Research | Minimal Risk

Principal Investigator (PI) | Dr. Shafic Sraj

Department | WVU Department of Orthopaedics

Co-Investigator(s) | Dr. Andrea Lese, Dr. Joseph Prudhomme, and Dr. John Taras, Dr. Andrew Wroblewski

WVU IRB Protocol # | 2103263450

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

Introduction

You have been asked to participate in this research study, which has been explained to you by an authorized member of the research team. This study is being conducted by Dr. Shafic Sraj in the Department of Orthopaedics at West Virginia University, along with Dr. Andrea Lese, Dr. Joseph Prudhomme, Dr. Andrew Wroblewski, and Dr. John Taras.

Purpose

The purpose of this study is to determine whether one of two current standard of care corticosteroid injections for trigger finger is more beneficial for the patient than the other. WVU expects to enroll approximately 100 subjects. A total of approximately 80-100 subjects, at all sites, are expected to participate in this study.

Description of Procedures

This study involves being asked to answer a single survey question at multiple time-points: immediately after the injection, five minutes after the injection, and once daily for the following week up to 14 days, and will take approximately 1 minute to complete.
You will be randomly chosen for one of two standard of care injection groups. Both corticosteroid injections are currently offered as standard of care choices by the hand surgeons.

Risks and Discomforts

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

In addition, there is always the risk of uncommon or previously unknown side effect(s) or event.

Alternatives

You do not have to participate in this study. If you choose not to participate, you will still receive a corticosteroid injection as part of the normal standard of care procedures.

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Benefits

You may or may not directly benefit from participating in this research. The knowledge gained from this study may eventually benefit others.

Financial Considerations

There is no financial compensation for your participation in this study.

Your data, health information, research results, or any and all other information related to this research study used in this research study may contribute to a new discovery or treatment. In some instances, your data, your health information, your research results, your specimens, these discoveries or treatments, or any other information related to this research study, even if identifiers are removed, may be of commercial value and may be sold, patented, or licensed by the investigators and West Virginia University for use in other research or the development of new products. You will not retain any property rights nor will you share in any money or commercial profit that the investigators, West Virginia University, or their agents may realize.

Confidentiality

Any information about you that is obtained as a result of your participation in this research will be kept as confidential as legally possible. Your research records and test results, just like hospital records, may be subpoenaed by court order or may be inspected by the study sponsor or federal regulatory authorities, including the Food and Drug Administration (FDA), without your additional consent.

In addition, there are certain instances where the researcher is legally required to give information to the appropriate authorities. These would include mandatory reporting of infectious diseases, mandatory reporting of information about behavior that is imminently dangerous to you or to others, such as suicide, child abuse, etc.

In any publications that result from this research, neither your name nor any information from which you might be identified will be published without your consent.

Your identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

HIPAA Authorization

We know that information about your health is private. We are dedicated to protecting the privacy of that information. Because of this promise, we must get your written authorization (permission) before we may use or disclose your protected health information or share it with others.

You can decide to sign or not to sign this authorization section. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Whatever choice you make about this research study will not have an effect on your access to medical care.

Persons/Organizations Providing the Information

Patient (record review, phone call), West Virginia University Hospitals, WVU Medicine, WVUHS (data are from records)

Persons/Organizations Receiving the Information

- The research site(s) carrying out this study. This includes UHA or UHA Affiliates, WVU, WVU Hospitals, West Virginia University Health System (WVUHS). It also includes each site's research and medical staff.

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- Health care providers who provide services to you as part of this research study.
- Laboratories and other people and groups that look into your health information as part of this study in agreement with the study protocol.
- The members and staff of any institutional review board that oversees this research study.
- The West Virginia University Office of Human Research Protection and the West Virginia University Office of Sponsored Programs.
- WVU Department of Orthopaedics, Hand Service

The Following Information Will Be Used

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).

The Information is Being Disclosed for the Following Reasons

- Review of your data for quality assurance purposes
- Publication of study results (without identifying you)
- Other research purposes such as reviewing the safety or effectiveness of the study drug and other products or therapies; conducting performance reviews of the study drug; evaluating other products or therapies for patients; developing a better understanding of disease; improving the design of future clinical trials.

You may Cancel this Authorization at Any Time by Writing to the Principal Investigator

The Principal Investigator, Dr. Shafic Sraj, may be reached via email at shafic.sraj@hsc.wvu.edu or by phone at 304-293-3007. The Study Coordinator, Jenn Eicher, may be reached at jeicher@hsc.wvu.edu or 304-285-7445.

If you cancel this authorization, any information that was collected already for this study cannot be withdrawn. Once information is disclosed, according to this authorization, the recipient may re-disclose it and then the information may no longer be protected by federal regulations.

This authorization will expire at the end of the study unless you cancel it before that time.

Voluntary Participation

Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time. Termination of study participation can be done by contacting the Study Coordinator Jenn Eicher, at jeicher@hsc.wvu.edu. If you choose to withdraw your participation from the study, the data collected on you up until that time remains a part of the study database and may not be removed. No additional information will be added to the study database after your withdrawal.

Refusal to participate or withdraw will not affect your future care or status at West Virginia University.

In the event new information becomes available that may affect your willingness to participate in this study, this information will be given to you so that you can make an informed decision about whether or not to continue your participation.

Contact Persons

If you have any questions, concerns, or complaints about this research, you can contact the Study Coordinator, Jenn Eicher, at 304-285-7445.

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If you are hurt from being in this research, you should contact Dr. Shafic Sraj at Shafic.sraj@hsc.wvu.edu or 304-293-3007. If injury occurs outside of business hours and is related to your participation in this research, please contact Dr. Sraj at 304-293-3007.

For information regarding your rights as a participant in research or to talk about the research, contact the WVU Office of Human Research Protection (OHRP) at (304) 293-7073 or by email at IRB@mail.wvu.edu.

Future Contact

Future research may be conducted for which you are eligible. If you are interested in being contacted for future research, please indicate so by completing this section.

☐ Yes, I want to be contacted if future research studies, for which I am qualified, become available.

☐ No, I **do not** want to be contacted if future research studies, for which I am qualified.

Signatures and Authorization

You have been given the opportunity to ask questions about the research (if applicable) and your authorization of HIPAA, and you have received answers concerning areas you did not understand. Upon signing this form, you will receive a copy.

Participant Signature

I willingly consent to participate in this research.

Signature of Subject or Subject's Legal Representative

Printed Name Date

Consenting Individual Signature

The participant has had the opportunity to have questions addressed. The participant willingly agrees to be in the study.

Signature of Person Obtaining Informed Consent

Printed Name Date

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