DSUVIA Early Evaluation of Pain (DEEP) Trial

NCT05288348

Approved 12/18/2023

University of Pittsburgh

CONSENT FOR PARTICIPATION IN RESEARCH

STUDY TITLE: DSUVIA™ Early Evaluation of Pain (DEEP) Trial: Task Order 0008

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SOURCES OF SUPPORT: This study is funded by the Department of Defense (DOD)

KEY INFORMATION

You are being asked to participate in a research study that is being done to compare the effectiveness, safety, and acceptability of DSUVIA™ to standard care pain treatment in injured patients with moderate to severe pain. This consent provides you with information so you can decide if you want to participate in the study. Your participation in this study is voluntary. You do not have to participate in the study to get treatment for your pain.

If you choose to participate, you will receive either a one-time dose of DSUVIA™ (30 micrograms in tablet form) in a tablet under your tongue or standard care pain treatment in the Emergency Department (ED). DSUVIA™ is an opioid medication, like morphine or fentanyl, but given by a different route. You may still receive additional standard care pain medication if needed after receiving DSUVIA™. You will be asked to complete some questions about your pain during your ED stay for up to 2 hours, until you are discharged, or until you receive additional pain medication whichever comes first. You will be paid $25.00 in a Vincent Pay card upon your completion of the study.

The risks of participating in the study include possible side effects of pain medication, including low blood pressure, low oxygen level, nausea, vomiting, headache, or dizziness. Other risks are from a risk to confidentiality.

We are unsure if there are benefits of one method of pain treatment over another. Your participation may help us better understand treatment of trauma injuries in the future.

The alternative to participating in this study is to receive standard medical care without collection of your medical information for research.

If you are interested in learning more about this study, please continue to read below.

INTRODUCTION

You are receiving this consent because you are eligible for a research study. Before you decide if you want to take part in this study, you need to understand the risks and benefits of this study. This is known as informed consent. This consent form provides information about the research study that has been explained to you. Once you understand the study and what is required, you will be asked to sign this form if you would like to participate in the study. Your decision to take part in the study is voluntary. This means you are free to choose. This research study will enroll 150 injured patients with moderate to severe pain at the University of Pittsburgh and UPMC. You would be asked to answer some questions about your pain from the time that you received study medication until up to two hours later, when you are discharged, or when you receive additional pain medication, whichever comes first. We would also collect information from your medical records during your hospital stay.

DSUVIA™ is approved by the U.S. Food and Drug Administration to treat adults with moderate to severe pain in a healthcare setting where alternative treatments are inadequate but is not available in the ED for treatment of pain outside of this research study.

Your doctor may be involved as an investigator in this research study. Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not obligated to be part of any research study offered by your doctor.

PURPOSE OF THE STUDY

This study is being done to compare the effectiveness, safety, and acceptability of DSUVIA™ to standard care pain treatment in an ED setting in injured patients with moderate to severe pain.

If you agree to participate, you may receive either DSUVIA™ in a tablet form that dissolves under your tongue or usual care. A randomization process (like flipping a coin) will be used to determine which pain medication you receive. Depending on the randomization, you may or may not receive DSUVIA™. All other medical care provided to you will be standard medical care for your condition.

We would like to collect information by asking you to complete some questions about your pain during your ED stay. We would also like to collect information from your medical records to follow up on your health during your hospital stay and the treatment that you receive while in the hospital. The reason for getting this information is to better understand how the type of pain treatment that you received impacted your recovery. This information may include time spent in the hospital and the type of care you received, information such as date of birth, age, gender, test results, medications, medical procedures, and any illnesses or setbacks you experience while you are in the hospital. We will collect information about how each of your body systems is doing by recording lab values and procedures that are done as part of your care. We will collect information from your record throughout your hospitalization until you are discharged. Your permission to access your health records for the purposes of this study does not expire.

Your data may be shared with other scientists and researchers outside of UPMC/University of Pittsburgh. Your name and identifying information will be removed from the data and it will be replaced with a unique code before they are sent to anyone.

RESEARCH PROCEDURES

If you decide to take part in this research study, you will undergo the following procedures that are not part of your standard medical care:

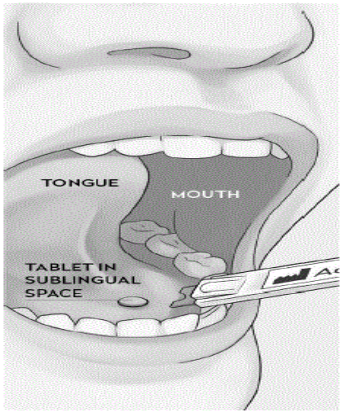
You will receive either DSUVIA™ or standard care pain medication. A randomization process (like flipping a coin) will be used to determine which you receive. DSUVIA™ is approved by the U.S. Food and Drug Administration to treat adults with moderate to severe pain in a healthcare setting where alternative treatments are inadequate but is not available in the ED for treatment of pain outside of this research study.

1. You will receive one dose of pain medication after you have been randomized. You will receive either:

Standard care pain medication given one time.

OR

DSUVIA™ tablet (30 micrograms) given one time under your tongue using an applicator. You will be asked to let the tablet dissolve under your tongue.



2. You will be asked to complete some questions about your pain and how you are feeling every 30 minutes for up to 2 hours, until you are discharged, or until you receive additional pain medication, whichever comes first.

3. We will record information from your hospital records about your health and the treatment that you receive during your hospital stay.

POTENTIAL RISKS AND DISCOMFORTS

Participation in this study may expose you to certain risks and discomforts. The risks of being enrolled in this study are related to receiving DSUVIA™ instead of standard care pain treatment, which may include opioids. DSUVIA™ contains sufentanil, which is an opioid.

The risks of receiving opioid pain treatment include:

Common side effects include nausea, vomiting, or dizziness.

Less common side effects include allergic reaction, blood pressure changes, changes in heart rate, difficulty breathing or stopping breathing, and muscle rigidity.

Opioids expose users to the risks of addiction, abuse, and misuse. Serious or life-threatening, or fatal respiratory depression has been reported with the use of opioids.

Rare side effects include serotonin syndrome (agitation, hallucination) and adrenal insufficiency (low level of hormones).

Infrequent side effects of receiving DSUVIA™ include:

- Headache
- Flushing

- Hiccups
- Decrease in urination
- Increased liver enzymes
- Sleepiness
- Insomnia
- Mental status changes
- Euphoria
- Disorientation
- Anxiety
- Constipation
- Passing gas
- Indigestion
- Dry mouth
- Burping
- Abdominal distention or discomfort
- Numbness in mouth

As with any experimental procedure, there may be adverse events or side effects that are currently unknown and certain of these unknown risks could be permanent, severe, or life threatening.

An additional risk of participation in this study is a risk to confidentiality, which is discussed in a paragraph below.

ANTICIPATED BENEFITS TO SUBJECTS
We are conducting this study to compare giving DSUVIA™ to standard care treatment for pain and are unsure if there are any benefits to one over the other. You may not receive any direct benefit from taking part in this research study. Because DSUVIA™ is a tablet taken by mouth, you may benefit by not needing to receive pain treatment through an IV in your vein. Ultimately your participation may help us better understand treatment of trauma injuries in the future.

ALTERNATIVES TO PARTICIPATION
The alternative to participating in this study is to receive standard medical care without collection of your medical information for research.

PAYMENT FOR PARTICIPATION
You will be paid $25.00 in a Vincent Pay card at the completion of your participation in the study.

All compensation is taxable income to the participant regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 76% of the expected payment.

COSTS OF PARTICIPATION
There are no additional costs to you for participating in this study. For patients who are randomized to receive DSUVIA™, the cost of DSUVIA™ will be covered by the study. Clinical care provided will be charged in the usual manner as part of your standard medical care (care you would receive even if you were not participating in this research study).

MEDICAL CARE FOR RESEARCH RELATED INJURY
UPMC and their associates who provide services at UPMC recognize the importance of your voluntary participation in their research studies. These individuals and their staff will make reasonable efforts to minimize, control, and treat any injuries that may arise because of this research. If you believe that you are injured because of the research procedure being performed, please immediately contact the principal investigators listed on the first page of this form.

Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that the hospital may bill your insurance provider for the costs of this emergency treatment but none of these costs will be charged directly to you. If your research related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated above. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

CONFIDENTIALITY

We make every effort to keep the information about you confidential. You will be assigned a study code number. This code number, and not your name, is used on all the data we collect. The data collected may be shared with other doctors and research scientists outside of the University of Pittsburgh/UPMC. A key linking you to the code number is kept in a secure location and will be available only to investigators and their research teams. The data will be retained indefinitely and may be used for future studies. Data from this study, without your identity, may be reported in scientific meetings, articles, or other appropriate communications.

If you sign this document, you give permission for access to your health information that identifies you for the research study to the investigators listed on the first page of this consent form and their research staff. In addition, authorized representatives of the University of Pittsburgh Office of Research Protections, the Department of Defense, and the FDA may access your research records as part of their responsibility to protect human subjects in research. In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

Authorized representatives of the University of Pittsburgh/UPMC or other affiliated health care providers may have access to your identifiable information (which may include your identifiable medical record information) for the purpose of (1) fulfilling orders, made by the investigators, for hospital and healthcare services (such as laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; (3) for internal hospital operations (i.e. quality assurance).

SUBJECT ACCESS TO RESEARCH RESULTS

A description of this clinical trial will be available on www.clinicaltrials.gov as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

PARTICIPATION AND WITHDRAWAL

Your participation in this research is voluntary. If you choose not to participate, that will not affect your relationship with your providers or your right to health care or other services to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and discontinue further participation at any time without prejudice. Research information obtained as part of this study before the date that you withdrew your consent will continue to be used by the investigators for the purposes described above. If you want to withdraw, notify the study team.

CONSEQUENCES OF WITHDRAWAL

If you choose not to participate, we will not collect any information from your medical record.

WITHDRAWAL OF PARTICIPANT BY THE INVESTIGATOR
The investigator may withdraw you from participation in this research if circumstances arise which warrant doing so. The investigator may make the decision and let you know it is not possible for you to participate. This decision may be made either to protect your health and safety, or because your condition did not meet the criteria needed for study inclusion.

IDENTIFICATION OF INVESTIGATORS
In the event of a research related injury or if you experience an adverse reaction, please immediately contact the Principal Investigator or Co-Principal Investigator listed on the first page of this form.

RIGHTS OF RESEARCH SUBJECTS
You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research subject, you may contact the Human Subjects Protection Advocate University of Pittsburgh (1-866-212-2668).

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SIGNATURE OF RESEARCH SUBJECT
VOLUNTARY CONSENT

The study has been explained to me and all of my questions have been answered. I understand that, throughout my participation in this research study, I am encouraged to ask questions about any aspect of this research study including the use and disclosure of my identifiable medical record information. Any additional questions or concerns about any aspect of this study will be answered by the investigators listed on the first page of this form.

I understand that I may always request that my questions, concerns, or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the Human Research Protections Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing this form, I agree to participate in this research study and provide my authorization to share my medical records with the research team. A copy of this consent form will be given to me.

_____	_____	_____	_____
Participant's Signature	Printed Name of Participant	Date	Time

INVESTIGATOR CERTIFICATION

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the subject or their representative or family member and any questions about this information have been answered.

Physician Investigator Signature	Physician Investigator Name (Print)	Date	Time