

ICF

Postoperative Antibiotic Management Duration Following Surgery for
Intravenous Drug Abuse (IVDA) Endocarditis (OPTIMAL)

NCT05156437

15-Dec-2021

Key Information for:

OPTIMAL

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 the safety and compliance of initial intravenous (IV) antibiotic followed by oral antibiotic therapy following uncomplicated intravenous drug abuse (IVDA) endocarditis.
- You will be asked to agree to be randomized (like flipping a coin) to complete the standard of care therapy or be assigned to the experimental therapy. In both groups, you will have weekly monitoring of your blood antibiotic levels and will also have use of an electronic compliance monitoring application called MEDISAFE.
- Your participation in the study is expected to last two (2) months.

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 recurring infection, lack of infection resolution, and/or adverse drug reaction. In addition, there is always the risk of uncommon or previously unknown side effect(s) or event(s).

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 withdrawal from the study, you can contact Vinay Badhwar, MD at 304.598.6092 from the Department of Cardiovascular and Thoracic Surgery at West Virginia University.

For more information, please see the Informed Consent Form.

Informed Consent for Research | More than Minimal Risk

Principal Investigator (PI) | Vinay Badhwar, MD
Department | Department of Cardiovascular & Thoracic Surgery
Sponsor or Funding Source | NIH CTSN CRISP
WVU IRB Protocol # | 2109416021
Study Title | PostOperative AnTibiotic MAnagement Duration FoLLowing Surgery for Intravenous Drug Abuse (IVDA) Endocarditis (OPTIMAL)

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 Vinay Badhwar, MD in the Department of Cardiovascular and Thoracic Surgery at West Virginia University. Funding for this research is provided by National Institutes of Health (NIH) Cardiothoracic Surgical Trials Network (CTSN) Clinical Research and Implementation Skills Program (CRISP) Award.

Purpose

The purpose of this study is to determine the safety and compliance of initial intravenous (IV) antibiotics followed by oral antibiotic therapy following uncomplicated IVDA endocarditis. Endocarditis has a high rate of sickness and death, involves a long hospitalization and a long-term use of IV antibiotics necessitating six (6) weeks of in-patient hospital stay, and comes with a high cost. A total of approximately twenty (20) subjects, are expected to participate in this study.

Description of Procedures

This study involves being treated for your condition through the normal standard of care or a different schedule of care and your participation is expected to last approximately two (2) months.

You have endocarditis and are undergoing surgical therapy. By taking part in this study, you will be randomly assigned (like flipping a coin) to either receive the standard of care treatment group, which is six (6) weeks of IV antibiotics while staying in the hospital or the experimental group which is two (2) weeks of IV antibiotics in the hospital and four (4) weeks of oral antibiotics not in the hospital. Both groups of subjects will have access to addiction services as in-patient for two (2) weeks followed by weekly counseling sessions as in-patient or out-patient in controlled manner. You will have weekly monitoring of your blood antibiotic levels and will also have use of an electronic compliance monitoring application called MEDISAFE.

Risks and Discomforts

You may experience recurrence, lack of infection resolution, and/or adverse drug reaction. In addition, there is always the risk of uncommon or previously unknown side effect(s) or event(s).

Radiation Risk

The amount of radiation (x-rays and scans to assess your disease) that you are exposed to in this study is considered standard of care for your disease. The risks of these procedures will be explained to you by your doctor and staff involved in your care. Risks from radiation exposure are cumulative (they increase) over time.

Alternatives

You do not have to participate in this study.

Benefits

Your health may improve as a result of participating in this study, but since it is not known if it will be effective in your case, you may not receive any benefit or your condition may worsen. The knowledge gained from this study may eventually benefit others.

Financial Considerations

There are no special fees for participating in this study, but most expenses associated with current therapy or treatment of side effects will be billed to you or to your insurance company. There is one laboratory test to measure the antibiotics in your blood that will be paid for by the study. Everything else is associated with your standard of care therapy and will be billed to your insurance.

You will be compensated \$50.00 for each week completed in the study for a total of up to \$300.00. You will only be paid for the weeks you complete. You will be provided a reloadable gift card at the beginning of your participation and monies will be loaded onto that card as you complete your weekly participation.

Your information may be provided to the appropriate parties for billing and/or payment purposes. Please be advised that any compensation received for participation in a research study, including a gift card, is considered taxable income and must be reported to the Internal Revenue Service (IRS).

Your data, health information, research results, specimens, 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 information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

ClinicalTrials.gov

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this Web site at any time.

HIPAA Authorization

We know that information about your health is private. We are dedicated to protecting your privacy and information. Because of this promise, we will need your written authorization (permission) before we use or disclose any of 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/West Virginia University Hospitals/WVU Medicine/WVUHS

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.
- 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 United State Department of Health and Human Services (which includes the National Institutes of Health (NIH), Food and Drug Administration (FDA)) and other groups that have the right to use the information as required by law.
- 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.
- Department of Cardiovascular and Thoracic Surgery; Department of Medicine, Section of Infectious Disease.

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 physicals, clinic visit notes, nursing and staff notes, laboratory results, x-rays, EKG results, demographic data, pulmonary tests, imaging scans, and study forms.

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 and other products or therapies; conducting performance reviews of the study; 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

Vinay Badhwar, MD
WVU Medicine
One Medical Center Drive
Box 8500
Morgantown, WV 26506

Only written cancelation of Authorization is permissible.

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.

You have a right to see and make copies of your medical records. You will not be able to see or copy your records related to the study until the work related to the study is completed. At that time, you may ask to see the study doctor's files related to your participation in the study and have the study doctor correct any information about you that is wrong.

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

Voluntary Compensation

There is no money set aside to help treat you if you get hurt or sick in this study. The study doctor and WVU or its partners do not have special funds to pay for research related injuries if they occur.

If you are injured as a result of this research, treatment will be available. This care will be billed to you or your insurance company. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the investigator, Vinay Badhwar, MD at 304.598.6092 if you are injured or for further information.

Voluntary Participation

Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time. 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.

Your participation in the study may be changed or terminated based on the discretion of the study doctor.

Contact Persons

If you have any questions, concerns, or complaints about this research, you can contact Vinay Badhwar, MD at 304.598.6092.

If you are hurt from being in this research, you should contact Vinay Badhwar, MD at 304.598.6092. If injury occurs outside of business hours and is related to your participation in this research, please contact Study Personnel at 304-598-4478.

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 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 and authorization of HIPAA.

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