Comparing **O**ral versus **P**arenteral **A**ntimicrobial **T**herapy (COPAT) Trial

NCT05977868

Informed Consent Form

June 12, 2024

Medical Informed Consent for Research
Key Information for:
Comparing Oral versus Parenteral Antimicrobial Therapy (COPAT) Trial

You are being asked to participate as a human subject in the research described below. This page provides a summary of the research that may help you to decide whether you wish to participate. More detailed information can be found in the Informed Consent Form beginning on the next page.

What is the study about and how long will it last?

- The purpose of this study is to determine if early transition from intravenous (IV) to oral antibiotics is safer while treating your infection successfully as well compared to continued outpatient IV antibiotics.
- You will be asked to agree to be randomized (like flipping a coin) to be discharged with oral antibiotics or outpatient IV antibiotics to complete treatment for your infection. As a part of either group (and per usual care), you will receive telephone calls to see how you are doing, have weekly lab tests for monitoring, and follow up in person or by telephone or video in Infectious Diseases (ID) Clinic.
- Your participation in this study is expected to last 3 months after you are discharged from the hospital.

Do you have to participate, and what are the benefits and risks?

Participation in this research study is entirely voluntary, and you are free to withdraw from the research at any time. If you do not wish to participate, please discuss alternatives with Joy J. Juskowich, MD, or Arif R. Sarwari, MD, MSc, MBA, or refer to the "Alternatives" section in the consent form. If you choose to withdraw your participation from the research study, the data collected about you will remain a part of the research database and may not be removed. No additional information will be added to the database after you withdraw.

Benefits from participation may include leaving the hospital sooner or having lower risk of complications related to IV access if you are randomized to the group discharged with oral antibiotics. Knowledge gained from this study may eventually benefit others.

Risks from participation in this study include: adverse events related to antibiotics or IV access, lack of infection resolution, or infection recurrence (same as with usual treatment for your infection). Other possible risks and discomforts include experiences associated with IV antibiotic use such as need for IV access, more time required to take each dose, and number of doses per day. Similarly, possible risks and discomforts associated with oral antibiotic use may include experiences associated with pill size and number of doses per day. IV and oral antibiotics have similar side effects.

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

If you have any questions or concerns about this research or wish to withdraw, you can contact:

Research Study Contact Name: Joy J. Juskowich, MD, or Arif R. Sarwari, MD, MSc, MBA, from West Virginia University (WVU) Department of Medicine, Section of ID, at 304-293-3306 (Ext. 3) or jjuskowi@hsc.wvu.edu. Business Hours: Monday-Friday 9:00 AM-4:30 PM.

For more information, please review the Informed Consent Form on the next page.

Medical Informed Consent for Research

Principal Investigators (PIs) |	Joy J. Juskowich, MD, and Arif R. Sarwari, MD, MSc, MBA
Department |	WVU Department of Medicine, Section of ID
Co-Investigator(s) |	Jesse Thompson, PhD, John Guilfoose, MD, Allison Lastinger, MD, Jonathan Stanley, DO, Connie Smith, MD, FAAP, Victor Arcega, MD, Seyoum Bage, MD
Sponsor or Funding Source |	WVU Department of Medicine
WVU IRB Protocol # |	2304754420
Research Study Title |	Comparing Oral versus Parenteral Antimicrobial Therapy (COPAT) Trial

Introduction

You have been asked to participate in this research study. The research has been explained to you by an authorized member of the research team.

This research is being conducted by Joy J. Juskowich, MD, and Arif R. Sarwari, MD, MSc, MBA, from WVU Department of Medicine, Section of ID. Funding for this research is provided by WVU Department of Medicine.

What is the purpose of this study?

The purpose of this research is to determine if early transition from intravenous (IV) to oral antibiotics is safer while treating your infection as well compared to continued outpatient IV antibiotics. For serious infections including heart infections and bone and joint infections, early transition from IV to oral antibiotics has been shown to be as good as IV antibiotics only. IV antibiotics after you leave the hospital are associated with challenges including need for IV access and possible complications. Oral antibiotics that reach high blood levels may be used in place of IV antibiotics.

All medications used in this study are approved by the Food and Drug Administration (FDA) for the treatment of serious infections.

WVU expects to enroll approximately 135 participants in the research study across 5 participating WVU Medicine hospitals.

What will you be asked to do?

If you decide to take part, this is what will happen:

This research study involves being treated for your infection at the time of your hospital discharge with oral antibiotics or outpatient IV antibiotics. You will be followed for approximately 3 months.

If you are being asked to participate in this research study, you have been diagnosed with an infection. By taking part in this research study, you will be randomized (like flipping a coin) to receive either oral antibiotics only from the time of hospital discharge or outpatient IV

antibiotics, which may be any of the following: IV antibiotics only, IV antibiotics changed to oral antibiotics later (sometime after hospital discharge), or longer-acting IV antibiotics. As a part of either group (and per usual care), you will receive telephone calls to see how you are doing, have weekly lab tests for monitoring, and be followed by an Infectious Diseases (ID) physician on the research team with in-person or telemedicine ID Clinic visits at 2, 6, and 12 weeks after hospital discharge.

If your infection is not improving or you are having major side effects, your treatment may be changed to IV antibiotics (if receiving oral) or oral antibiotics (if receiving IV).

At the 6-week ID Clinic follow-up, you will be asked to complete a short patient satisfaction survey expected to take 5 minutes or less. You may skip any questions you do not wish to answer and stop taking the survey at any time. You may request to access and review the patient satisfaction survey prior to signing this Informed Consent Form.

Incidental Findings

As part of usual care, any clinically relavent medical information such as results from lab tests and routine ID care will be discussed with you during follow-up calls or ID Clinic visits.

What are the possible risks and discomforts?

As is the case with standard of care antibiotic treatment for infection, risks from participating in this study include adverse events related to antibiotics or IV access, lack of infection resolution, and/or infection recurrence. There is always the risk of uncommon or previously unknown side effect(s) or adverse event(s). Other possible risks and discomforts include experiences associated with IV antibiotic use such as need for IV access, more time required to take each dose, and number of doses per day. Similarly, possible risks and discomforts associated with oral antibiotic use may include experiences associated with pill size and number of doses per day. IV and oral antibiotics have similar side effects.

If you don't want to take part in this study, are there other choices?

An alternative would be to not participate in this study. Participation in this study is voluntary; you do not have to participate.

Will you benefit from taking part in this study?

You may or may not directly benefit from participating in this research. Benefits from participation may include leaving the hospital sooner or having lower risk of complications related to IV access if you are randomized to the group discharged with oral antibiotics. The knowledge gained from this research may eventually benefit others.

What will it cost you to participate?

There are no additional costs for participating in this research study.

Participants should consult with their insurance carrier before participation. Any expense associated with current therapy or treatment of side effects will be billed to you or your insurance company the same way as it would be if you were not participating in this research study.

Will you receive any payment for taking part in this study?

You will be paid $50 in the form of a gift card for participating in this study and attending your ID Clinic follow-up visit 12 weeks after hospital discharge. Your visit may be in person or by telephone or video. If you do not participate in your ID Clinic follow-up visit 12 weeks after hospital discharge, you will be paid $0. For more information regarding the method of payment, contact the Principal Investigators.

Unless the research is confidential or awarded an NIH Certificate of Confidentiality, you may be asked to provide your Social Security Number and verification of U.S. Citizenship or Permanent Resident Status to receive payment.

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 is considered taxable income and must be reported to the Internal Revenue Service (IRS). A form 1099 will be sent to you if your total payments for research participation are $600 or more in a calendar year.

Your data, health information, research results, specimens, genomic data, or any and other information related to this research or used in this research study may contribute to a discovery or treatment. In some instances, your data, your health information, your research results, your specimens, the discoveries or treatments, or any other information related to this research study (even if identifiers are removed) may be of commercial value. The information may be sold, patented, or licensed by the Principal Investigators, and West Virginia University for use in other research or the development of new products. You will not retain any property rights, and you will not be eligible to share in any monetary or commercial profit that the Principal Investigators, West Virginia University, or their agents may realize.

Who will see the information that you give?

We will keep your information as confidential as possible. However, if the law requires that we disclose your confidential information, every effort will be made to limit the use and disclosure of the information. Your name will not be used in the publication of information about the research.

Your research records and test results, just like hospital records, could be subpoenaed by court order or may be inspected by the study sponsor or federal regulatory authorities without your additional consent.

There are instances where the researcher is legally required to provide information to the appropriate authorities. This could include the mandatory reporting of infectious diseases and information about behavior that is imminently dangerous to you or others, such as suicide, child abuse, etc.

All data collected in this research study including records identifying the pateints will be kept safe and secure. Any physical copies of data collected will be kept in a locked drawer or file cabinet within a locked room or office. Digital data will be stored on a password protected database or drive. All information that may be used to identify you will be stored separately from data collected.

Regarding the patient satisfaction survey, we will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data transmitted via the Internet. Third-party applications used in this study may have Terms of Service and Privacy policies outside of the control of West Virginia University. We will be using a secure web-based data collection tool designed for research (REDCap).

Will your information be used for future research?

Your information or biospecimen collected as part of this research, even if identifiers are removed, will not be used or distributed for future research.

ClinicalTrials.gov

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

HIPAA Authorization

West Virginia University is dedicated to protecting the privacy of your information. As part of the protection, we are required to obtain your written authorization (permission) before we may use or disclose your protected health information (PHI) or share it for research purposes.

You can decide to sign or not to sign this authorization. However, if you choose not to sign this authorization, you will not be able to take part in the research. The choice you make about participation in this research study will not affect your access to medical care.

Persons/Organizations Providing the Information:
Data will be obtained from both of the following:
Patient – Data is obtained from the participant.
West Virginia University Hospitals\WVU Medicine\WVUHS – Data is obtained from medical 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), and other affiliate sites, including the research and medical staff at the site(s).
- Health care providers who provide services to you as part of this research study.
- Laboratories and others that view your health information as part of this study in agreement with the study protocol.
- U.S. 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 the Institutional Review Board that oversees this research study.
- The West Virginia University Office of Human Research Protections and the West Virginia University Office of Sponsored Programs.
- The WVU Department of Medicine, Section of ID.

The Following Information Will Be Used:
This information could include new or existing information about you, such as demographic data, history and physicals, progress notes, consultation notes, operative reports, clinic visit notes, laboratory results, microbiology results, x-rays and other imaging results, cardiovascular study results, 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 or therapies, conducting performance reviews of the study, evaluating other therapies for patients, developing a better understanding of infectious diseases and their treatment, and/or improving the design of future clinical trials.

You may cancel this HIPAA Authorization at any time by writing to the Principal Investigators.
All cancellations must be in writing.

Principal Investigators' Names: Joy J. Juskowich, MD, and Arif R. Sarwari, MD, MSc, MBA
Mailing Address: P.O. Box 9163, Morgantown, WV 26506

If you cancel this Authorization, any information that has been collected for the research study to date 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 research study until all work related to the study has been completed. At that time, you may ask to see the information related to your participation and request corrections to the information.

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

What happens if you get hurt or sick during the study?

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 from WVU 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 Principal Investigators, Joy J. Juskowich, MD, or Arif R. Sarwari, MD, MSc, MBA, at 304-293-3306 (Ext. 3) during business hours or 304-598-4000 after business hours if you are injured or sick (related to participation) for further information.

Who should you contact if you have questions or concerns?

If you have any questions, concerns, or complaints about this research, contact

Principal Investigators' Names: Joy J. Juskowich, MD, and Arif R. Sarwari, MD, MSc, MBA

Telephone Number: 304-293-3306 (Ext. 3)

Business Hours: Monday-Friday 9:00 AM-4:30 PM

If an injury occurs or you become sick (related to participation), contact

During Business Hours

Principal Investigators' Names: Joy J. Juskowich, MD, and Arif R. Sarwari, MD, MSc, MBA

Telephone Number: 304-293-3306 (Ext. 3)

Outside of Business Hours

Principal Investigators' Names: Joy J. Juskowich, MD, and Arif R. Sarwari, MD, MSc, MBA

Telephone Number: 304-598-4000

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

Do you have to participate in this study?

Participation in this research study is voluntary. You are free to withdraw your consent to participate at any time. f you withdraw or do not wish to participate, your future care or status at West Virginia University will not be affected.

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

If you choose to withdraw your participation from the research study, the data collected about you will remain a part of the research database and may not be removed. No additional information will be added to the database after you withdraw.

For WVU Students as participants:

If you do not wish to participate or if you choose to withdraw, your class standing, and grades will not be affected and will involve no penalty to you.

For WVU Employees as participants:

If you do not wish to participate or choose to withdraw, your employment status at West Virginia University will not be affected.

Do you want to be contacted with information about future studies?

Future research may be conducted for which you may be eligible. If you are interested in being contacted for future research, please indicate so by completing this section. Leaving the box blank is seen as **NOT** giving consent.

☐ Yes, I want to be contacted.

☐ No, I **do not** want to be contacted.

Signatures

Participant Signature Section

I willingly consent to participate in this research and applicable authorizations. Upon signing this form, you will receive a copy.

Printed Name:

_____

Signature:

_____

Date:

Legally Authorized Representative Signature Section (delete this section if not applicable)

The participant is unable to give informed consent. I, as the legally authorized representative of the participant, give consent for their participation in this study.

Printed Name:

_____

Signature:

_____

Date:

_____

Consenting Individual Signature Section (Authorized Staff)

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

Printed Name:

_____

Signature:

_____

Date:

_____