Official Title: Aerosolized Antibiotics in the Treatment of Ventilator Associated Pneumonia: A Pilot Study

NCT #: NCT02478710

Document Date: September 17, 2018

Approved
17-Sep-2018
Expires
16-Sep-2019

INFORMED CONSENT AND RESEARCH AUTHORIZATION

Aerosolized Antibiotics in the Treatment of Ventilator Associated Pneumonia: A Pilot Study

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Site(s) where study is to be conducted: Miami Valley Hospital

Phone number for subjects to call for questions: (937) 208-2552

Introduction and Background Information

You are invited to take part in a research study because you have been diagnosed with pneumonia associated with being on a breathing machine. The study is being conducted under the direction of John Bini, M.D., Principal Investigator. 50 local subjects will be invited to take part in this research.

Purpose

The purpose of this study is to determine if inhaling antibiotics directly into the lungs leads to better improvement and decreased recurrence of pneumonia related to when compared to intravenous (IV) antibiotics alone.

Procedures

Your participation in this study will last for the duration of treatment for pneumonia associated with being on a breathing machine, a minimum of 7 days. If you consent to participate, you will have the following procedures while you are in this study:

(i) Bronchoscopy with bronchoalveolar lavage- a camera will be placed through the breathing tube and into the airways to look at the lungs and take fluid samples to send to the lab **OR** a combicath will be performed- saline solution will be inserted through a protected tube into lungs and then will be suctioned out quickly to obtain sample
(ii) Routine blood sampling for labs.
(iii) Nebulized treatments (inhaling) of either study antibiotics or placebo (salt water)

Patients will be assigned to the control group or study group randomly by a computer. All patients will receive the standard intravenous antibiotics. Control group patients will receive inhaled salt water (placebo) treatments. Study group patients will receive inhaled antibiotic treatments. All patients will have a bronchoscopy with bronchoalveolar lavage or combicath (described above) and blood sampling.

Potential Risks

Potential risks of the study include the following:

(i) Risks of bronchoscopy or combicath: low oxygen levels, fever, abnormal heart rhythms, bleeding, collapsed lung, death
(ii) Risks of study antibiotics:

- Linezolid: allergic reaction, low blood cell counts, low platelets, changes in vision, changes in sensation, seizures, diarrhea, colon infection
- Piperacillin/tazobactam: allergic reaction, skin rash or blisters, diarrhea, colon infection, low blood cell counts, bleeding, low potassium levels, seizures
- Vancomycin: allergic reaction, low blood pressure, skin rash or blistering, kidney injury, hearing changes, low blood cell counts, diarrhea, colon infection, inflammation of the veins
- Tobramycin: changes in hearing, balance disturbance, kidney injury, allergic reaction, skin rash or blistering, kidney injury, dizziness, hearing changes

(iii) Blood sampling: bleeding, bruising, skin or blood stream infection

Benefits

The possible benefits of this study include higher rate of improvement of ventilator associated pneumonia and decreased recurrence of pneumonia. There is no guarantee that you will personally benefit from this research.

Alternatives

Instead of taking part in this study, you could choose to receive standard of care treatment or comfort care treatment, and not participate in this study.

Research Related Injury

If you are injured by being in this research study, the investigator will arrange for you to get medical treatment. Neither Wright State University, the study site, nor the investigator has set aside money to pay for treatment of any injury. You and your insurance will be billed for the treatment of these injuries. Before you agree to take part in this research study you should find out whether your insurance will cover an injury in this kind of research. You should talk to the investigator or staff about this. If you are injured, there is no money set aside for lost wages, discomfort, disability, etc. You do not give up your legal rights by signing this form. If you think you have a research related injury, please call the investigator at (937) 208-2552.

Compensation

You will not be compensated for your time, inconvenience, or expenses while you are in this study.

Costs

There may be additional costs to you for participating in this research study over the usual costs of your routine care outside of this research study. You will not be billed for the following office visits, tests, medications, and procedures that are done for this research study: study-specific antibiotics, study placebo, nebulizer, or study-specific blood tests.

Additionally, you or your insurance company will be billed for all office visits, tests, medications and procedures that are part of your routine medical care outside of this research study. You will be responsible for paying your co-pay that is associated with any office visit, test, medication or procedure. Some insurance companies will not pay for medical bills for people who participate in a research study. It is your responsibility to find out what costs, if any, your insurance company will cover before taking part in the study. If you need help finding out what your insurance company will cover, please ask the investigator or staff for assistance. If your insurance company does not pay for your bills associated with this study, you will be responsible for paying them.

HIPAA Research Authorization

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides federal safeguards for your protected health information (PHI). Examples of PHI are your name, address, and birth date together with your health information. PHI may also include your medical history, results of health exams and lab tests, drugs taken and results of this research study. Your PHI may not be used or shared without your agreement, unless it meets one of the HIPAA exceptions.

State and federal privacy laws protect your health information. In most cases, health information that identifies you can be used or shared by the research team only if you give your permission by signing this form.

If you sign this form your health information will be used and shared to answer the research questions described above and to make sure that the research was done correctly. The time period when information can be used or shared ends when all activities related to this study are completed.

Your access to your health information will be limited during this study. When the study is over, you will have the right to see your health information related to this research.

You do not have to sign this form. If you do not sign this form you may not participate in the study and health information that identifies you will not be shared with the research team.

Revocation of Research Authorization

You may cancel the permission you have given us to use and share your protected health information at any time. This means you can tell us to stop using and sharing your protected health information. If you cancel your permission:

- We will stop collecting information about you.
- You may not withdraw information that we had before you told us to stop.
    - We may already have used it or shared it.

- We may need it to complete the research.
- Staff may ask your permission to follow-up with you if there is a medical reason to do so.

You may cancel your permission by writing to the investigator at the address on page one.

Information Available on 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 website will include a summary of the results. You can search this website at any time.

Confidentiality

Total privacy cannot be guaranteed. We will protect your privacy to the extent permitted by law. If the results from this study are published, your name will not be made public.

Your information may be shared with the following:

- The appointed Data Safety Monitoring Board related to the study
- The Wright State IRB and Office of Research and Sponsored Programs
- The local research team
- People responsible for billing, sending and receiving payments related to your participation in the study
- People who are responsible for research and HIPAA oversight at Miami Valley Hospital

Data Security

Data collected will be de-identified and assigned a patient number. Paper documents will be stored in a locked cabinet. Electronic data will be stored on password-protected computers on PHP server at Miami Valley Hospital.

Conflict of Interest
The Principle Investigator and study researchers have no financial interests to disclose.

Voluntary Participation

Taking part in this study is completely voluntary. You may choose not to take part at all. If you decide not to be in this study, you won't be penalized or lose any benefits for which you qualify. If you decide to be in this study, you may change your mind and stop taking part at any time. If you decide to stop taking part, you won't be penalized or lose any benefits for which you qualify. You will be told about any new information learned during the study that could affect your decision to continue in the study.

Termination

The investigator, the IRB or the study sponsor has the right to stop this study at any point. The investigator may take you out of this study with or without your permission. Reasons why this may occur include:
Allergy or reaction to study antibiotics
Presence of antibiotic resistant organisms

Participation in Other Research Studies

You may not take part in this study if you are currently in another research study. It is important to let the investigator know if you are in another research study.

Research Subject's Rights, Questions, Concerns, and Complaints

If you have any questions or concerns about the research study you may contact the principal investigator, John Bini, MD, at (937) 208-2552.

If you have any questions about your rights as a study subject, questions or concerns, you may call the Wright State IRB Office (937) 775-4462. You may discuss any questions about your rights as a subject with a member of the IRB or staff. The IRB is an independent committee composed of members of the University community, staff of the institutions, as well as lay members of the community not connected with these institutions. The IRB has reviewed this study.

Acknowledgment and Signatures

This form tells you what will happen during the study if you choose to take part. Your signature means that this study has been discussed with you, that your questions have been answered, and that you will take part in the study. This informed consent document is not a contract. You are not giving up any legal rights by signing this informed consent document. You will be given a signed copy of this consent to keep for your records

Printed Subject Name	Signature of Subject	Date Signed

Legally Authorized Representative (Please Print)	Signature of LAR	Date Signed

Relationship of Legally Authorized Representative to Subject

Signature of Person Obtaining Consent	Date Signed