SUMMARY OF RESULTS



The Antibacterial Resistance Leadership Group (ARLG) funds, designs, and conducts clinical research that will help prevent, diagnose, and treat infections caused by bacteria that are resistant to antibiotics.

The ARLG, along with the team of study doctors, scientists, and researchers, are pleased to describe the results from a study focused on antibiotic review strategies in community hospitals to prevent overuse of antibiotics.

What is the study title?

Short-course Therapy and the Antibiotic Resistome (STAR)



MANUSCRIPT OF PRIMARY RESULTS OR CLINICAL STUDY REPORT.

Comparison of the Respiratory Resistome in Children Receiving Short vs. Standard Course Treatment for Community Acquired Pneumonia

and

Gastrointestinal Microbiome Disruption and Antibiotic-Associated Diarrhea in Children Receiving Antibiotic Therapy for Community-Acquired Pneumonia

IS THE STUDY REGISTERED WITH CLINICALTRIALS.ORG?

NCT02891915



WHY WAS THIS RESEARCH CONDUCTED? WHAT IS THE RATIONALE?

Due to the increased use of antibiotics, antibiotic resistance is a public health issue. CAP in children is often treated with 10 days of antibiotics. Researchers would like to learn whether shorter treatment plans

are as effective. If so, this could potentially help decrease and combat the problem of antibiotic resistance.

CAP is one of the most common serious infections in children. Diarrhea is a common side effect of antibiotics and a common reason why people stop using antibiotics as prescribed. Researchers are interested in learning about the specific microorganisms in the gut associated with diarrhea in children receiving antibiotics for CAP.

Changes to your healthcare should not be made based on information in this summary without first consulting a doctor. If you have questions about these results, speak with your doctor.



WHAT IS THE PURPOSE OF THE RESEARCH?

Pneumonia is an infection

that inflames the air sacs in the lungs. Symptoms can include chest pain, cough, fever, and difficulty breathing. Pneumonia is caused by a range of bacteria and viruses and infection can be mild or severe and sometimes can be fatal.

The STAR study focuses on community-acquired pneumonia (CAP), meaning it is an infection in the community setting (not from the hospital). The goal of the STAR study is to learn more about the side effects and duration of antibiotic treatment for CAP.

The first manuscript studied the impact of antibiotic duration (5 days vs 10 days) on microorganisms in the respiratory tract and antibiotic resistance. Resistance is when bacteria develop the ability to defeat the drugs designed to kill them.

The second manuscript focused on the microorganisms in the gut and diarrhea in children receiving antibiotics for CAP.





WHEN DID THE RESEARCH TAKE PLACE?

From December 2, 2016 to December 16, 2019



WHO WAS INVOLVED?

The first analysis included data from 171 children, ages 6 to 71 months.

The second analysis included data from 66 children (n=198 samples), ages 6-71 months.

All study sites were located in the United States.





WHAT HAPPENED DURING THE STUDY?

In both of these analyses, all the children had received antibiotics for the treatment of CAP. In the first analysis, throat swabs were collected and the number of bacterial

resistance genes were analyzed.

In the second analysis, stool samples were collected and analyzed for bacterial DNA to look for links between microorganisms in the gut and diarrhea related to antibiotic use.



HOW WILL THE RESULTS HELP PATIENTS AND DOCTORS?

Longer than necessary use of antibiotics can lead to antibiotic resistance in individual children as well as in the population as a whole. Shorter number of treatment days is

simpler for the child.

The results of these analyses show that antibiotic use should be decreased whenever possible. This research also identifies microorganisms related to antibiotic side effects (diarrhea).



WHY IS THIS RESEARCH IMPORTANT TO PATIENTS, CLINICIANS, AND OTHER RESEARCHERS?

Antibiotics (particularly

beta-lactam antibiotics, such as amoxicillin, amoxicillin-clavulanate, and cefdinir) are commonly given as treatment for CAP in children. The standard treatment is for 10 days,

but use of antibiotics for long periods of time can lead to resistance. Reducing the use of antibiotics potentially reduces the presence of antibiotic resistant bacteria, which can be passed on from one person to another.



Therefore, understanding more about this will help reduce antibiotic resistance in the individual child as well as in the general population. Shorter days of antibiotic treatment that is still effective can also reduce side effects (such as diarrhea) and resistance.



WHAT WERE THE RESULTS?

Children receiving standard 10 days of antibiotic therapy for CAP had more antibiotic resistance genes for a longer

period of time than children receiving 5 days of therapy.

In the second analyses, researchers found that children with specific microorganisms in the gut are more likely to have diarrhea after antibiotic use. Children who had diarrhea after receiving antibiotics had an imbalance in the normal gut bacteria for a longer period of time.



WHAT'S NEXT?

Researchers are using the information from these analyses to inform additional research in antibiotic use in CAP, to design clinical trials

using new strategies to decrease resistance, and to help inform treatment decisions that improve the outcomes of children.

