# **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 short course antibiotic therapy for children with community-acquired pneumonia (CAP).

#### WHAT IS THE STUDY TITLE?

Short Course Outpatient Antibiotic Therapy for Community-Acquired Pneumonia in Children

## MANUSCRIPT OF PRIMARY RESULTS OR CLINICAL STUDY REPORT.

https://clinicaltrials.gov/ct2/show/results/NCT02891915



## IS THE STUDY REGISTERED WITH CLINICALTRIALS.ORG?

NCT02891915

https://clinicaltrials.gov/ct2/show/NCT02891915



## WHAT IS THE PURPOSE OF THE RESEARCH? WHAT IS THE PRIMARY ENDPOINT?

The purpose of this study was to learn if a shorter five-day antibiotic treatment strategy would work better than the typical 10-day

strategy to treat children under six years of age with community-acquired pneumonia (CAP).

Researchers collected information on each patient's results including how well people responded to the antibiotic treatments, whether symptoms improved, and any negative effects. They used methods called Response Adjusted for Duration of Antibiotic Risk (RADAR) and Desirability of Outcome Ranking (DOOR) to sort and rank the information. These methods provide ways to help researchers analyze and compare types of information from clinical trials.

At the end of each patient's treatment, researchers also used throat swabs to measure the number of antibiotic resistant genes (ARGs). Having fewer ARGs could mean there are fewer drug-resistant bacteria present.

## WHY WAS THIS RESEARCH CONDUCTED? WHAT IS THE RATIONALE?



Community-acquired pneumonia (CAP) is a common and serious infection that leads to 1.5 million doctor visits in the United States each year. Doctors usually treat CAP with a

seven to 10-day course of antibiotics, but it can have negative effects.

Information from other studies has shown that antibiotic treatment strategies shorter than 10 days can work well to treat CAP in children. However, these studies did not look at all the possible negative effects from the antibiotics or the possible harm of unnecessary antibiotic use.

Researchers needed more information on the best way to treat CAP in children. This study helped them learn more about how well people responded to the antibiotic treatments, whether their symptoms improved, and if they had any negative effects.



## WHEN DID THE RESEARCH TAKE PLACE?

December 2016 to December 2019





#### WHO WAS INVOLVED?

Researchers studied 380 children age six months to less than six years old diagnosed with CAP and receiving outpatient antibiotic treatment. The study took place in eight research sites in the United States.

380 Children

Research sites in the United States



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

It is common for doctors to treat CAP with a seven to 10-day course of antibiotics, but it can have negative effects.

Another concern is that overusing antibiotics has increased the number of drug-resistant bacteria called "superbugs" worldwide.

Limiting how long patients take antibiotics could lessen these negative effects and help doctors combat the spread of drug-resistant bacteria.



## WHAT HAPPENED DURING THE STUDY?

Otherwise healthy children who were receiving antibiotics for CAP were asked to participate in the study within their first five days of therapy.

The study divided participants into two groups called the Short Course group and the Standard Course group.

#### **SHORT COURSE**

Received 5 days of antibiotics + 5 days of placebo

#### **STANDARD COURSE**

Received 10 days of antibiotics

Researchers evaluated information from both groups two different times using the RADAR and DOOR methods. They recorded the patient's overall responses to treatment, symptoms, and any negative effects of the antibiotics.

During the second evaluation, researchers collected a throat swab from the participants to test for antibiotic resistance genes (ARGs).



## HOW WILL THE RESULTS HELP PATIENTS AND DOCTORS?

This research study has helped provide researchers with evidence to support a short course five-day treatment strategy in young children with CAP

who show early clinical improvement. Using a shorter treatment strategy would be more convenient for patients and would help reduce antibiotic use that can cause antibiotic resistance.



#### WHAT WERE THE RESULTS?

Researchers evaluated and recorded each patient's:

- Response to treatment
- Persistent symptoms
- Negative events related to the antibiotic.

Researchers found there were no significant differences between the Short Course group and Standard Course group for these three measures individually or when compared together.

Next, the researchers compared the length of the antibiotic treatment in the two groups using the RADAR method. RADAR gives researchers a way to compare two participants who have the same result. In this analysis, the Short Course group had a more desirable RADAR outcome.

Further analysis of the throat swabs showed that the Short Course group had significantly fewer Antibiotic Resistant Genes (ARGs).

Overall, the short course five-day treatment strategy was superior to the standard course 10-day treatment strategy. The short course strategy led to similar clinical outcomes while reducing antibiotic exposure and resistance.



#### **WHAT'S NEXT?**

More research is needed to study the short course five-day treatment strategy in older children, as well as those with underlying medical conditions or more severe illness.

