

SUMMARY OF RESULTS



DOTS

Antibacterial Resistance Leadership Group

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 improving antibiotic treatment options for bloodstream infections.

WHAT IS THE STUDY TITLE?

Dalbavancin as an Option for Treatment of *S. aureus* Bacteremia (DOTS)



MANUSCRIPT OF PRIMARY RESULTS OR CLINICAL STUDY REPORT

[Dalbavancin for Treatment of *Staphylococcus aureus* Bacteremia: The DOTS Randomized Clinical Trial](#)

IS THE STUDY REGISTERED WITH CLINICALTRIALS.ORG?

[NCT04775953](#)



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

Researchers for the DOTS study wanted to learn if two doses of dalbavancin, a long-lasting antibiotic often used to treat severe, bacterial skin infections, could work better than the standard intravenous (IV) antibiotic treatment for patients hospitalized for complicated *Staphylococcus aureus* (staph or *S. aureus*) bloodstream infections. Intravenous (IV) means the medicine is given to a patient directly through a vein.

The researchers monitored participants to determine how well their staph infections improved and whether they experienced any symptoms or complications from the medicine. The team used the ARLG's Desirability of Outcome Ranking (DOOR) method to look at how patients were doing 70 days after their infections.

DOOR is designed to provide information from studies that doctors can later use to create better, customized treatment plans for patients. DOOR looks at both how well a treatment works and what side effects patients might have during treatment.



WHY WAS THIS RESEARCH CONDUCTED? WHAT IS THE RATIONALE?

S. aureus is the leading cause of death from bacterial bloodstream infections in the world.¹ Patients diagnosed with severe bloodstream infections typically receive IV antibiotics through a peripherally inserted central catheter (or PICC line) for four to six weeks. Although this is the standard treatment option, the use of a long-term PICC line can cause complications like blood clots and other infections.

One potential alternative, dalbavancin, is a long-acting antibiotic that may be able to treat complicated *S. aureus* bloodstream infections without a long-term PICC line.

Although there is some information from studies on the use of dalbavancin to treat staph bloodstream infections, the results have been encouraging but uncertain. The goal of the DOTS study was to give doctors better information about dalbavancin compared to the standard therapy option. This information can help doctors create better treatment plans for complicated *S. aureus* bloodstream infections.

¹GBD 2019 Antimicrobial Resistance Collaborators. Global mortality associated with 33 bacterial pathogens in 2019: a systematic analysis for the Global Burden of Disease Study 2019. *Lancet*. 2022;400(10369):2221-2248. doi:10.1016/S0140-6736(22)02185-7



ARLG

Antibacterial Resistance Leadership Group



WHEN DID THE RESEARCH TAKE PLACE?

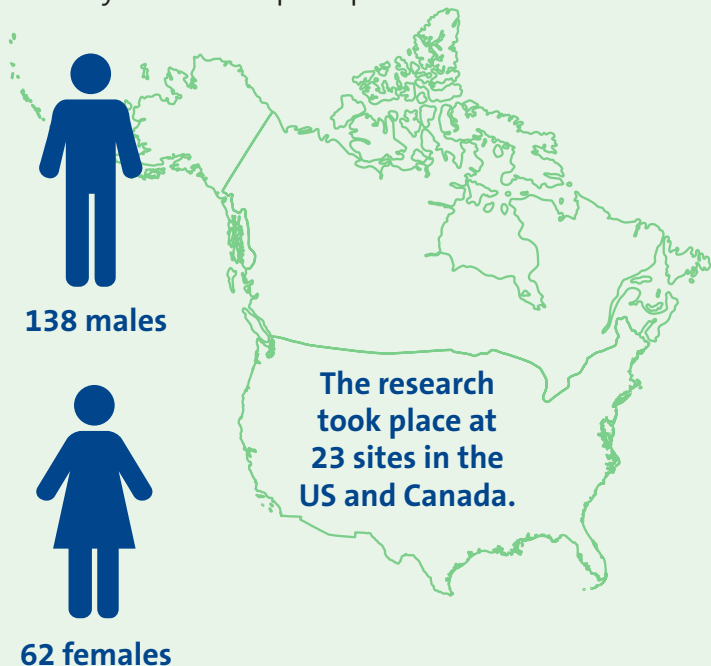
April 2021 – December 2023



WHO WAS INVOLVED?

People taking part in the DOTS study were in the hospital with complicated *S. aureus* bloodstream infections. They were 18 years of age or older and had a median age of 56.

The study included 200 participants:



WHAT HAPPENED DURING THE STUDY?

The DOTS study involved 200 adult participants with severe *S. aureus* bloodstream infections who were randomly assigned (like the flip of a coin) to one of two groups. The first

group received two doses of dalbavancin one week apart. The second group received the standard antibiotic treatment through a PICC line for four to six weeks.

After 70 days, researchers collected information on the safety of both treatments as well as patients' symptoms and quality of life. They used the ARLG's DOOR method to determine the results.



WHAT WERE THE RESULTS?

The study results showed that although dalbavancin was not better at treating bloodstream infections, it worked as well as the standard therapy with fewer patients having to stop or change

treatment due to side effects.

The DOOR analysis showed that 73 of the 100 participants who received dalbavancin had an overall successful result compared to 72 of the 100 participants receiving the standard PICC line therapy.

Participants who received two doses of dalbavancin had a lower risk of complications from PICC lines and required less lab monitoring and home health care.



HOW WILL THE RESULTS HELP PATIENTS AND DOCTORS?

The standard treatment for serious staph bloodstream infections requires the use of a long-term PICC line which can cause health complications like blood clots or other infections. In addition to these

risks, the standard IV therapy may require hospitalization or specialized home health care which can impact patients' ability to move around and their quality of life.

Serious *S. aureus* bloodstream infections are common and can be deadly. Both patients and doctors can benefit from having an additional treatment option that is equally effective without many of the risks involved with long-term PICC lines.



The DOTS study helps doctors and patients by providing meaningful information that can help guide doctors' treatment decisions when considering dalbavancin for serious staph bloodstream infections.



WHAT'S NEXT?

Compared to the standard PICC line treatment for serious staph bloodstream infections, dalbavancin may offer an easier treatment option for patients and reduce the need for home health care.

The DOTS research team is conducting a separate study to learn which treatment option is less expensive overall.