Why is this study important?

Pediatric Acute Bacterial Skin and Skin Structure Infections are responsible for thousands of hospital visits every year, as bacterial infections across the world continue to rise. These infections need to be treated with antibiotics, which makes it important to continue to develop treatments that are safe and effective for more children.

Pharmaceutical companies use studies like this one to learn more about investigational drugs before they are made available to the public. The results of this study will provide more information about the investigational drug. By participating in this study, your child will be making an important contribution to skin infection treatment research.

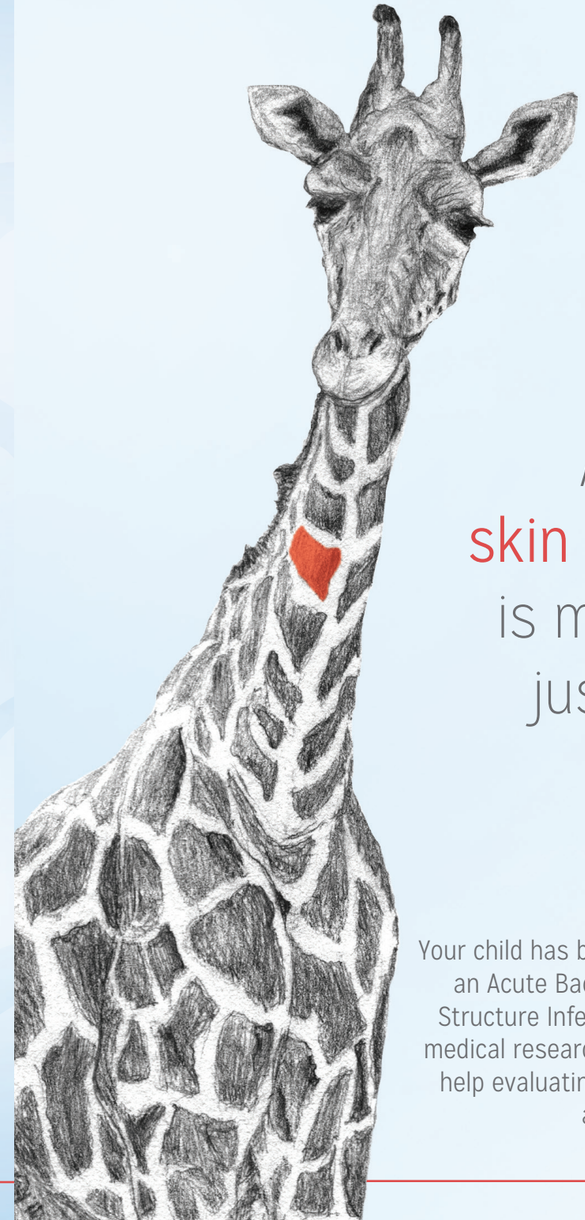
To learn more about this study, please contact:

<<Contact Name>>
<<Contact Number>>

spot

Study of a Pediatrics skin infectiOns Treatment

08Mar2022_V3_DUR001-306_Parent Brochure_English



A serious skin infection is more than just a spot.

Your child has been diagnosed with an Acute Bacterial Skin and Skin Structure Infection or sepsis. This medical research study needs your help evaluating an investigational antibiotic treatment.

Your child's doctor believes that your child may have a skin infection called Acute Bacterial Skin and Skin Structure Infection (ABSSSI) or sepsis (infection in the blood). This type of infection can become serious and needs to be treated as soon as possible.

There are several antibiotic treatment options available to your child, including this research study of an investigational antibiotic drug that may require less dosing than current treatment options.

In this study, doctors want to evaluate how well the investigational drug works against ABSSSI when compared to approved, standard antibiotic treatment. The investigational drug is called dalbavancin and is approved by the United States Food and Drug Administration (FDA) for the treatment of skin infections in adults and children. In Europe, the European Medicines Agency (EMA) has approved dalbavancin for the treatment of skin infections in adults only. It is not approved to treat skin infections in children in Europe.

The results of this study will help doctors learn more about the investigational drug and whether it could be used to treat ABSSSI in children. Eligible patients will receive the investigational drug through an intravenous infusion (IV; needle inserted into a vein in the arm).

If your child has been diagnosed with an ABSSSI or sepsis and you are reviewing treatment options, please consider this research study.

Who is eligible to participate in this study?

To pre-qualify for the study, your child must:

- Be from birth to < 29 days
- Be showing signs and symptoms of an ABSSSI or sepsis
- Have a parent or legal guardian willing to give written informed consent

All study-related visits, tests and drugs will be provided at no cost. In addition, reimbursement for reasonable study-related expenses may be provided.

What will happen during this study?

Before a patient can participate in this study, he or she must be screened for eligibility. If your child is found to be eligible, and you agree to participate, your child will receive only a single-dose of the investigational drug.

Total study participation will last approximately 54 days (about 2 months). There will be 7 study visits, which will take place at the hospital. If your child's condition improves, the study doctor may allow your child to be discharged from the hospital, but you will be asked to return to the hospital for the remaining study visits.

What are the risks and benefits related to this study?

The investigational drug may help to improve your child's infection. However, it is not guaranteed or promised that your child will receive any benefit from this study.

It is possible your child may experience a side effect while in this study. In previous research studies with the investigational drug, the most common side effects were nausea (feeling sick), diarrhea, headache, rash, itching and vomiting.

Because research studies can affect the health and safety of participants, your child will be closely monitored during this study. Researchers for this study were required to design a protocol, which explains all study procedures in detail. An independent review board responsible for participant safety approved this protocol and requires that it be followed exactly.

What if I have questions?

The study staff is always available to answer any questions or concerns you may have about this study, the investigational drug, or the approved antibiotic treatments.