SOJTHWESTERN NEWS

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UT Southwestern researchers test experimental drug to help tiniest heart patients

DALLAS – Aug. 16, 2005 – UT Southwestern Medical Center is the only institution in the nation approved by the Food and Drug Administration to test an experimental drug on infants undergoing heart surgery to see whether it can help them avoid potentially lethal infections and improve survival.

The experimental drug, Neuprex – a Bactericidal Permeability Increasing (BPI) protein, fights bacterial poisoning, but was developed for adults and older children. UT Southwestern doctors will determine whether it might benefit infants and, if so, what dose is effective but still safe.

"It has potential to make a difference in a huge number of kids. We just don't know yet," said Dr. Erica Molitor-Kirsch, assistant professor of pediatrics and primary investigator of the National Institutes of Health-funded project. "It hasn't been used in infants undergoing heart surgery before."

Each year roughly 30,000 babies in the United States are born with congenital heart defects. About a third require open-heart surgery, during which the infants are placed on heart-lung machines. The procedure sometimes results in additional complications, such as inflammation, in which the babies become noticeably swollen.

"The organs most often affected by swelling are lungs, heart, kidneys and sometimes the brain," Dr. Molitor-Kirsch said.

Researchers suspect the swelling may result from endotoxin – a bacterial poison released into the bloodstream from normal intestinal bacteria.

"The inflammatory response to heart bypass may initially be triggered by endotoxin. This, in turn, sets off production of the other components of the inflammatory cascade, which may be harmful for children after heart surgery," said Dr. Daniel Stromberg, assistant professor of pediatrics at UT Southwestern and director of the Cardiac Intensive Care Unit at Children's Medical Center Dallas. "If, however, endotoxin is neutralized early in the operative process, thereby limiting the inflammatory response, postoperative complications may be reduced."

Doctors will track changes in vital signs and inflammatory mediators in the infants' blood to (MORE)

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determine whether the drug is working. They'll also see whether they are able to discontinue blood-pressure medicines and ventilators earlier by using Neuprex.

"The hope is that if they don't have all the swelling and problems with their lungs and heart, they can get off the ventilators and out of the ICU faster," said Dr. Molitor-Kirsch.

Investigators initially tested Neuprex on seven infants with no adverse side effects, but suspected higher doses might be needed. The new trial will include 24 patients, half receiving Neuprex and half serving as a control population. If that proves successful, the study will be expanded to 200 infants.

Researchers at UT Southwestern also are testing Neuprexin children with meningococcemia, a life-threatening bacterial infection. Another investigator is looking at the BPI protein as a possible aid to burn patients.

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