Multicenter trial aims to find if probiotics are safe, effective

July 3 2014, by Elizabethe Holland Durando

Washington University's David Schnadower is the principal investigator of a national clinical trial to determine whether a commonly used probiotic is safe and effective for young children being treated for gastroenteritis.

Consumers worldwide spend billions of dollars each year on probiotic foods and supplements. But studies evaluating probiotics—microorganisms believed to aid digestive health—have been limited.

To better understand probiotics' capabilities, researchers at Washington

University School of Medicine in St. Louis are leading a nationwide clinical trial to determine whether one of the most commonly used probiotics can safely and effectively treat infants and toddlers suffering from acute gastroenteritis, otherwise known as stomach virus or "stomach flu."

"Probiotics are very popular," said David Schnadower, MD, the trial's principal investigator and an associate professor of pediatrics at the School of Medicine. "People use them for everything, especially diarrhea, yet minimal data exist showing they really help. There is a real need to do a clear, definitive study of the use of probiotics in kids with gastroenteritis."

Probiotics are live microorganisms used to restore the balance of intestinal bacteria and increase resistance to harmful germs. They are added to yogurt, drinks and other foods and also are sold over the counter in pill and powder form.

While medical professionals sometimes give children with gastroenteritis medication to treat nausea and fluids to prevent dehydration, there are currently no treatments for the condition.

"We hope to provide evidence for or against the use of probiotics in children with stomach viruses," said Schnadower, who also treats patients at St. Louis Children's Hospital. "If the probiotic we are studying is helpful, safe and cost-effective, then I can foresee doctors prescribing it to children with diarrhea and other symptoms of gastroenteritis. But what we don't want is for the use of probiotics to become a practice that is not supported by evidence."

The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health (NIH) is funding the trial with a five-year $3.6 million grant.

The trial will involve about 900 children, ages 3 months to 48 months, treated at St. Louis Children's and at eight other academic medical centers.

Participants may be eligible if they come to the emergency room with symptoms of gastroenteritis: watery stools, vomiting, dehydration or other signs of acute intestinal infection. They also must not have taken probiotics in the preceding two weeks and must meet other criteria.

Children will be randomly assigned to receive a probiotic or a placebo for five days. The probiotic, approved by the Food and Drug Administration, is Lactobacillus GG, or LGG, which is sold over the counter as Culturelle. Otherwise, children in the trial will receive standard clinical care.

Researchers will assess patients by tracking the severity of their gastroenteritis, taking into account the duration and frequency of diarrhea and vomiting, the duration and height of fever, and the use of health-care resources such as doctor or hospital visits and use of intravenous rehydration.

For the first five days after an emergency room visit and again at two weeks, researchers will monitor patients via symptom diaries and phone or Internet surveys. The researchers will follow up with parents at the one-, three-, six-, nine- and 12-month marks after the initial emergency room visit, to check on each child's health.

"Evidence-based medicine can be an elusive goal," said co-investigator Phillip I. Tarr, MD, the Melvin E. Carnahan Professor of Pediatrics at the School of Medicine. "It is terrific that David and his emergency medicine collaborators are trying to gather high-quality data on which to base our treatment decisions."

Schnadower said investigators also will examine the impact, if any, that probiotics have on household transmission of diarrhea and a range of economic data involving missed work, missed day care and even the cost of diapers.

Collaborators in the trial are Columbia University in New York, Northwestern University in Chicago, Children's National Medical Center in Washington, Children's Hospital of Michigan in Detroit, Cincinnati Children's Hospital Medical Center, Brown University in Providence, R.I., University of Michigan in Ann Arbor and UC Davis Children's Hospital in Sacramento, Calif. The trial is conducted under the auspices of the Pediatric Emergency Care Applied Research Network, and the data center is at the University of Utah.

A similar trial in Canada examining the safety and efficacy of another common probiotic—Lacidofil—will coincide with the U.S. study. That trial, funded by the Canadian Institutes of Health Research, also will involve young children with gastroenteritis.

"Not only will we be able to know whether one probiotic is effective versus placebo, we also likely will be able to combine our data and learn whether one probiotic is more effective," Schnadower said.

More information: More information about the trial is available online: pediatrics.wustl.edu/probioticstudy/Home.aspx

Provided by Washington University School of Medicine in St. Louis